Expert Report of Daniel Salmon, Ph.D., MPH

Professional Experience

Dr. Salmon is a Professor of Global Disease Epidemiology and Control, Department of International Health, Johns Hopkins University Bloomberg School of Public Health. He also has a joint appointment in the Department of Health, Behavior and Society. Dr. Salmon serves as the Director of the Institute for Vaccine Safety at Johns Hopkins.

Dr. Salmon is broadly trained in vaccinology, with an emphasis in epidemiology, behavioral epidemiology, and health policy. Dr. Salmon received a Bachelor of Arts (BA) in Political Science with a minor in Psychology from Rutgers University in 1991. He received a Master of Public Health (MPH) from Emory University Rollins School of Public Health in 1996. Dr. Salmon received a Doctor of Philosophy (PhD) from Johns Hopkins University Bloomberg School of Public Health in 2003.

Dr. Salmon has held positions in government and academia. Dr. Salmon has worked for the Centers for Disease Control and Prevention as a contractor and later as a Policy Analyst. In these positions, he used surveillance systems to conduct studies of measles and pertussis and coordinated Federal efforts around vaccine safety, immunization information systems, and development of new vaccines such as for tuberculosis. Dr. Salmon also served as the Director of Vaccine Safety, National Vaccine Program Office, Department of Health and Human Services. In this capacity, Dr. Salmon was responsible for coordinating and overseeing the nation's vaccine safety system including vaccine safety activities in the Department of Health and Human Services (National Institute of Health, Food and Drug Administration, Centers for Disease Control and Prevention, and Health Resources and Services Administration) other Federal Departments (Defense, Veterans Affairs, State), and non-federal partners including academia, industry, professional medical and public health associations, states and localities, and the public. Dr. Salmon led a Secretary's initiative in vaccine safety, oversaw the 2009 H1N1 vaccine safety program, and served as the Designated Federal Official for the National Vaccine Advisory Committee (NVAC) Vaccine Safety Working Group and the Advisory Commission on Childhood Vaccines (ACCV). Among other accomplishments, Dr. Salmon created the Post-Licensure Rapid Immunization Safety Monitoring (PRISM) Network to conduct active vaccine safety surveillance for the 2009 H1N1 immunization program. PRISM became an ongoing surveillance system for the Food and Drug Administration as a part of the Sentinel program.

Dr. Salmon has conducted a broad range of research in academia including research grants funded by the National Institutes of Health, Centers for Disease Control and Prevention, state health departments, the World Health Organization, Gavi, the Vaccine Alliance, the Robert Wood Johnson Foundation, and private industry including Walgreens, Pfizer, Merck and Crucell. Dr. Salmon has also served as a grant reviewer for the National Institutes for Health, Centers for Disease Control and Prevention, Food and Drug Administration, National Science Foundation, the Gates Foundation, as well as numerous other country federal health authorities. Dr. Salmon has taught and continues to teach a class in vaccine policy for two decades and also currently teaches a class in public health practice at Johns Hopkins University Bloomberg School of Public Health. Dr. Salmon has mentored numerous students and scientists, many of which now hold leadership positions in academia, government, and international organizations.

Dr. Salmon's research and practice work has included a broad range of studies examining the individual and community risks of vaccine refusal, the impact of laws and policies in increasing vaccination coverage and controlling vaccine preventable diseases, the reasons why patients and parents refuse vaccines, and the role of health care providers in impacting patient and parent vaccine decision-making. Dr. Salmon is widely considered a national and global expert in these areas. Dr. Salmon is a member of the Lancet Commission on Vaccine Hesitancy and served on a National Vaccine Advisory Committee Working Group on vaccine hesitancy.

Dr. Salmon has published more than 100 papers in top medical and public health journals including the New England Journal of Medicine, the Lancet, the Journal of the American Medical Association, Health Affairs, and Pediatrics. Dr. Salmon regularly serves as a peer reviewer for these and other high impact journals. He has been invited to give presentations at the National Foundation for Infectious Diseases, Federal advisory committees, and international meetings. Dr. Salmon has served as an expert witness for a variety of legal cases. Dr. Salmon's current curriculum vitae is attached (Appendix 1).

Dr. Salmon has been retained by Main Line Health. Dr. Salmon has reviewed the following materials provided by Main Line Health:

1) Main Line Health COVID-19 vaccination policy;
2) Religious Exemption form;
3) Medical Exemption form; and
4) Pregnancy Deferral Form (added in September 2021.

The client has not impacted the content of this report. All opinions herein are that of Dr. Salmon. Dr. Salmon has been compensated at a rate of $450 per hour for time spent preparing this report.

Dr. Salmon was requested by the Defendant to provide opinions on the following issues:

1. Covid threat to patients and employees in September 2021
a. In September 2021, was COVID-19 a potentially fatal disease, particularly for vulnerable populations?
b. How did asymptomatic transmission impact the spread of COVID-19 in health care facilities?
c. Was exposure to COVID-19 in health care setting an occupational hazard for employees?
d. What was the impact of COVID-19 on health care system, patient access to care and care quality?
e. Why were health care personnel high priority group (#1a) when vaccines had limited availability?

2. Safety and Efficacy of COVID-19 Vaccines
a. What was the efficacy of vaccines available in September 2021?
b. In September 2021 were unvaccinated persons at an increased risk of contracting COVID and transmitting it to others who could not be vaccinated because of medical contraindications, were too young to be vaccinated or for whom the vaccine was not effective?

c. In September 2021, did the science indicate that "natural immunity" was as effective as vaccination?

3. Justification for mandatory Covid vaccine policy by health care institutions
a. September 2021, did Covid-19 pose a direct threat to patients and staff in health care facilities?
b. In September 2021, were mandatory COVID-19 vaccine policies a critical protective action for health care institutions to protect patients and staff?
c. Did anticipation of the upcoming flu season justify rollout of mandatory COVID-19 vaccine policy in September 2021?
d.Did mandatory COVID-19 vaccine policies pose risk that health care workers would choose to leave job rather than get vaccinated?
e.How did mandatory COVID-19 vaccine policies impact vaccine hesitancy?

4. Impact of medical and religious exemption requests on health care institutions
a. What were the clinical contraindications to receiving the COVID vaccine?
b. How did non-medical vaccine exemption requests impact the efficacy of vaccine requirements and patient safety?
c. Did exemptions seriously undermine the efficacy of a vaccination requirement?
d. Did health care institutions have a responsibility to patients and staff to establish and implement a process for evaluating exemption requests rather than simply rubber-stamping requests?
e. **How did exemptions impact the operations of the health care institutions**?
f.How effective were alternative infection control strategies (masking, testing, social distancing) in health care institutions?

5. Anti-vaccine movement's impact on mandatory vaccine policies
a. Was there an anti-vax movement that impacted COVID-19 vaccine hesitancy in September 2021?
b. What is the impact of the anti-vaccine movement on mandatory vaccine policies?

6. Stem cells: Some individuals who challenged mandatory COVID vaccine policies raised religious objections based on stem cell use in testing/development of vaccines
a. Which stem cell lines were used in testing the COVID-19 vaccines available in September 2021?
b. Other medicines for which stem cells were used in testing

Dr. Salmon's professional judgement in these areas is based upon review of current scientific evidence and federal advisory repots (referenced accordingly). However, at the request of counsel, data sources were limited to those available as of September 2021.

Covid threat to patients and employees as of September 2021

As of September 2021, was COVID-19 a potentially fatal disease, particularly for vulnerable populations?

As of September 2021, about 40 million cases of COVID-19 had been reported[1], about 2.9 million hospitalizations,[2] and about 675,000 deaths[3]. This month marked an unfortunate milestone, when the number of COVID-19 deaths had surpassed the number of deaths from the 1918 H1N1 influenza pandemic.[4] Hospitalizations and deaths were disproportionately impacting the elderly and those with chronic medical conditions such as diabetes, heart conditions and obesity.[5] However, even some young and healthy individuals were experiencing serious disease, hospitalization and death. Vulnerable racial/ethnic populations (Black, Hispanic and Native American) were also disproportionately impacted by COVID-19.[6] Delta (B.1.617.2) was the predominant variant in September 2021. COVID-19 was appearing in waves and varied substantially by locality, state and region, as often is the case with infectious disease.

How did asymptomatic transmission impact the spread of COVID-19 in health care facilities?

Asymptomatic transmission of COVID-19 in health care facilities was a major problem through September 2021. Many health care facilities were regularly testing staff. However, such tests were imperfect and testing frequency limits the value of testing in detecting asymptomatic infections. At this point, it was well accepted in the scientific community that asymptomatic persons were transmitting COVID-19.[7]

Was exposure to COVID-19 in health care setting an occupational hazard for employees?

Health care staff were at risk of occupational acquired COVID-19 through exposure to infected patients and other health care staff. The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) consequently prioritized health care workers for vaccination.[8] More than 3,600 health care workers died of COVID-19 in the first year of the pandemic.[9] The prevalence of SARS-CoV-2 infection among healthcare workers was 11%

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[1] Statista. Number of cumulative cases of COVID-19 in the United States from January 20, 2020 to November 11, 2022, by week. https://www.statista.com/statistics/1103185/cumulative-coronavirus-covid19-cases-number-us-by-day/ accessed 3/22/2023

[2] American Hospital Association. COVID-19 Snapshot Challenges Confronting America's Hospitals and Health Systems (September 9, 2021). https://www.aha.org/system/files/media/file/2021/09/snapshot-9-9-21.pdf accessed 3/22/2023

[3] CNN. The latest on the Covid-19 pandemic in the US. https://www.cnn.com/us/live-news/coronavirus-pandemic-vaccine-updates-09-20-21/index.html accessed 3/22/2023

[4] Centers for Disease Control and Prevention. 1918 Pandemic (H1N1 virus). https://www.cdc.gov/flu/pandemic-resources/1918-pandemic-h1n1.html access 3/22/2023

[5] Centers for Disease Control and Prevention. People with Certain Medial Conditions. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html accessed 3/22/2023

[6] Don Bambino Geno Tai, Irene G. Sia, Chyke A. Doubeni, Mark L. Wieland. Disproportionate Impact of COVID-19 on Racial and Ethnic Minority Groups in the United States: a 2021 Update. J Racial Ethn Health Disparities. 2022; 9(6): 2334–2339.

[7] Michael Johansson, Talia quandelacy, Sarah Kada et al. SARS-CoV-2 Transmission From People Without COVID-19 Symptoms. JAMA Netw Open. 2021;4(1):e2035057.

[8] Bell BP, Romero JR , Lee GM. Scientific and ethical principles underlying recommendations from the advisory committee on immunization practices for COVID-19 vaccination implementation. *JAMA.* 2020; 324: 2025-2026

[9] KHN. 12 Months of Trauma: More Than 3,600 US Health Workers Died in Covid's First Year. https://khn.org/news/article/us-health-workers-deaths-covid-lost-on-the-frontline/ accessed 3/25/23

in 2020, noticeably higher than in the general population.[10] Also in 2020, health care workers with direct patient care had 4 times this risk of contracting COVID-19 compared with health care workers without direct patient care.[11] In a large health care system of about 30,000 employees between June 1 to December 31, 2020, 2,357 employees were involved in occupational COVID-19 exposures; 1,128 (48%) were exposed to patients and 1,229 (52%) to other employees.[12]

COVID-19 had a tremendous impact on health care systems, patient access to care and quality of care. As COVID-19 spread across the country in waves, disproportionately impacting some communities and then moving on to others, health care systems struggled to keep up with patient demand. Health care capacity in the United States is generally designed to meet demand, often with rural health care facilities below community needs. As a consequence, the health care system was not well prepared for the surge on health care needs that resulted from COVID-19. The impact of COVID-19 on health care facilities was further strained by COVID-19 illness and death among health care workers and worker burn out. Health care systems attempted to respond by establishing surge capacity, including portable morgues in hospitals for COVID-19 deaths. Additionally, health care providers and facilities delayed routine and non-emergency procedures to free up capacity to address heath care needs related to COVID-19. The consequence was reduced access to care for patients and, in some cases, reductions in quality of care with increases in many diseases which were not diagnosed during routine care visits. For example, there were substantial drops in immunization coverage among children as routine visits were either virtual (not allowing for vaccination) or missed altogether. A study from Michigan indicated that among children aged 5 months, up-to-date vaccination status for all recommended vaccines declined from approximately two thirds of children during 2016–2019 to fewer than half in May 2020.[13] The long-term impact of rationing health care as a result of the COVID-19 pandemic will take many years to fully characterize.

Why were health care personnel a high priority group (#1a) when vaccines had limited availability?

The Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC) determined that health care personnel were the first priority for COVID-19 vaccine when it was available:

> **Phase 1a.** Health care personnel (HCP) are being considered for phase 1a, which includes the first available doses and an extremely constrained supply. HCP are defined as all paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials, comprising an estimated 20 million people. Examples include hospital, long-term care and assisted living, home health care, and

[10] Sergio Alejandro Gómez-Ochoa et al. COVID-19 in Healthcare Workers: A Living Systematic Review and Meta-analysis of Prevalence, Risk Factors, Clinical Characteristics, and Outcomes. Am J Epidemiol. 2020 Sep 1.

[11] Jonne Sikkens, David Buis, Edgar Peters et al. Serologic Surveillance and Phylogenetic Analysis of SARS-CoV-2 Infection Among Hospital Health Care Workers. JAMA Netw Open. 2021;4(7):e2118554.

[12] Jessica Ibiebele, Christina Silkaitis, Gina Dolgin et al. Occupational COVID-19 exposures and secondary cases among healthcare personnel. Am J Infect Control. 2021 Oct; 49(10): 1334–1336.

[13] Centers for Disease Control and Prevention. Decline in Child Vaccination Coverage During the COVID-19 Pandemic — Michigan Care Improvement Registry, May 2016–May 2020. MMWR. May 22, 2020 / 69(20);630–631.

outpatient facility staff, as well as pharmacies and emergency medical services. HCP are essential for the ongoing COVID-19 response and are at high risk for exposure to SARS-CoV-2.[14]

Health care personnel were the first priority for initial availability of COVID-19 vaccines for several reasons:

1) Health care personnel were at increased risk of contracting and transmitting COVID-19 because of their occupation exposure to COVID-19 cases;
2) Health care personnel were in regular contact with persons at increased risk of serious complications and death from COVID-19, including persons who were immunocompromised, had other comorbidities, and/or were elderly;
3) Health care facilities were often at or beyond capacity caring for persons with COVID-19 as well as other healthcare needs. As essential personnel, reducing the risk of health care personnel for contracting COVID-19 resulting in missed time from work and potentially morbidity and mortality was a local, state and national priority in order to maintain health care capacity; and
4) Given the sacrifice health care personnel were making to care for COVID-19 infected persons in addition to persons requiring other health care needs, it was equitable for health care personnel to receive all means available to protect themselves from COVID-19.

Safety and Efficacy of COVID-19 Vaccines

What was the efficacy of vaccines available as of September 2021?

The most accurate estimates of the efficacy of COVID-19 vaccines as of September 2021 were based on the information available from the phase 3 clinical trials that were consider by the Food and Drug Administration (FDA) and its Vaccines and Related Biological Product Advisory Committee (VRBPAC) which were made available to the public. At the time, there were three vaccines available through Emergency Use Authorization.

The Moderna COVID-19 vaccine (mRNA-1273) was authorized for use to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The Phase 3 randomized, double-blinded and placebo-controlled trial of mRNA-1273 included approximately 30,400 participants. The primary efficacy endpoint was the reduction of incidence of COVID-19 among participants without evidence of SARS-CoV-2 infection before the first dose of vaccine. Efficacy in preventing confirmed COVID-19 occurring at least 14 days after the second dose of vaccine was 94.5.0% (95% CI 86.5%, 97.8%). Subgroup analyses showed similar efficacy across age groups, genders, racial and ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19.[15]

[14] Bell BP, Romero JR , Lee GM. Scientific and ethical principles underlying recommendations from the advisory committee on immunization practices for COVID-19 vaccination implementation. *JAMA.* 2020; 324: 2025-2026
[15] Vaccines and Related Biological Products Advisory Committee Meeting. December 17, 2020. FDA Briefing Document. Moderna COVID-19 Vaccine. https://www.fda.gov/media/144434/download Accessed 03/26/23

The Pfizer and BioNTech COVID-19 vaccine (BNT162b2) was authorized for use to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The Phase 3 randomized, double-blinded and placebo-controlled trial of BNT162b2 included approximately 44,000 participants. The primary efficacy endpoint was incidence of COVID-19 among participants without evidence of SARS-CoV-2 infection before or during the 2-dose vaccination regimen. Efficacy in preventing confirmed COVID-19 occurring at least 7 days after the second dose of vaccine was 95.0%. Subgroup analyses showed similar efficacy across age groups, genders, racial and ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19.[16]

Janssen Biotech COVID-19 vaccine (Ad26.COV2.S) was authorized for use to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The Phase 3 randomized, double-blind and placebo-controlled trial of Ad26.COV2.S included approximately 40,000 participants. Vaccine efficacy against central laboratory-confirmed moderate to severe/critical COVID-19 was 66.9% (95% CI 59.0, 73.4) when considering cases occurring at least 14 days after the single-dose vaccination. Subgroup analyses showed similar efficacy across age groups, genders, racial and ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19.[17]

Using real world data among frontline workers between December 14, 2020–August 14, 2021 (Delta Wave), full vaccination with COVID-19 vaccines was 80% effective in preventing COVID-19.[18]

As of September 2021, were unvaccinated persons at an increased risk of contracting COVID and transmitting it to others who could not be vaccinated because of medical contraindications, were too young to be vaccinated or for whom the vaccine was not effective?

Based on the demonstrated efficacy of the Moderna, Pfizer and J&J COVID-19 vaccines in preventing disease[15,16,17] and reducing transmission to others (both by reducing the risk of infection and reducing the viral load if a breakthrough infection)[19,20], unvaccinated persons were at increased risk of contracting COVID-19 and transmitting to others who could not be vaccinated because of medical contraindications, were too young to be vaccinated or for whom the vaccine was not

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[16] Vaccines and Related Biological Products Advisory Committee Meeting. December 10, 2020. FDA Briefing Document. Pfizer-BioNTech COVID-19 Vaccine. https://www.fda.gov/media/144245/download Accessed 03/26/23.

[17] Vaccines and Related Biological Products Advisory Committee Meeting
February 26, 2021 FDA Briefing Document: Janssen Ad26.COV2.S Vaccine for the Prevention of COVID-19. https://www.fda.gov/media/146217/download. Accessed 03/26/23

[18] Centers for Disease Control and Prevention. Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020–August 2021. MMWR. August 27, 2021 / 70(34);1167-1169.

[19] David W Eyre, Donald Taylor, Mark Purver, David Chapman, Tom Fowler, Koen B Pouwels, A Sarah Walker, Tim EA Peto The impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission. https://doi.org/10.1101/2021.09.28.21264260

[20] Marc Shamier, Alma Tostmann Susanne Bogers et al. Virological characteristics of SARS-CoV-2 vaccine breakthrough infections in health care workers. Medriv. Aug 21, 2021. https://www.medrxiv.org/content/10.1101/2021.08.20.21262158v1

effective (as well at persons who were unvaccinated because they did not have access to the vaccines or decided to forgo vaccination).

As of September 2021, did the science indicate that "natural immunity" was as effective as vaccination?

Several studies were available at that time that indicated an immune response to COVID-19 that lasted for at least a short time,[21, 22,23] reduces the risk of reinfection, [24] and infections provided some level of protection among Rhesus monkeys.[25] However, good correlates of protection were not available. A correlate of protection is an "empirically defined, quantifiable immune parameters that determine the attainment of protection against a given pathogen".[26] In other words, it was not known what sort or how strong an immune response was necessary to protect from COVID-19, including but not limited to new variants that might emerge. So, it was measured that natural infection resulted in an immune response which lasted at least for months, it was not known if that immune response protected from COVID-19. Additionally, while there was some indication that infection reduces the risk of reinfection, there was not a good measure of how much it reduced reinfection nor for how long. A CDC study available in August of 2021 indicated that among previously infected persons, reinfection was about twice as high if not being fully vaccinated, leading CDC to recommend "To reduce their likelihood for future infection, all eligible persons should be offered COVID-19 vaccine, even those with previous SARS-CoV-2 infection."[27] Natural immunity also comes as the potential for morbidity and mortality from COVID-19. Monitoring of healthy individuals for more than 35 years had shown that reinfection with the same seasonal coronavirus occurred frequently[28] and protection from seasonal coronavirus infections are short lived.[29]

Justification for mandatory Covid vaccine policy by health care institutions

As of September 2021, did Covid-19 pose a direct threat to patients and staff in health care facilities?

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[21] Staines HM, Kirwan DE, Clark DJ, et al. IgG seroconversion and pathophysiology in severe acute respiratory syndrome coronavirus 2 infection. Emerg Infect Dis. 2021 Jan;27.
[22] Wajnberg A, Amanat F, Firpo A, et al. Robust neutralizing antibodies to SARS-CoV-2 infection persist for months. Science. 2020 Dec;370(6521):1227-1230.
[23] Dan JM, Mateus J, Kato Y, et al. Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection. Science. 2021 Feb 5;371(6529):eabf4063.
[24] Gallais F, Gantner P, Bruel T, et al. Anti-SARS-CoV-2 Antibodies Persist for up to 13 Months and Reduce Risk of Reinfection. medRxiv. 2021.
[25] Bao L, Deng W, Gao H, et al. Lack of Reinfection in Rhesus Macaques Infected with SARS-CoV-2. bioRxiv. 2020.
[26] Altmann DM, Douek DC, Boyton RJ. What policy makers need to know about COVID-19 protective immunity. The Lancet. 2020 May;395(10236):1527–1529.
[27] Centers for Disease Control and Prevention. Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021. MMWR. August 13, 2021 / 70(32);1081-1083.
[28] Om E, Byrne P, Walsh KA, et al. Immune response following infection with SARS-CoV-2 and other coronaviruses: A rapid review. Rev Med Virol. 2021 Mar;31(2):e2162.
[29] Edridge AWD, Kaczorowska J, Hoste ACR, et al. Seasonal coronavirus protective immunity is short-lasting. Nat Med. 2020 Nov;26(11):1691–1693.

As of September 2021, COVID-19 posed a direct threat to patients and staff in health care facilities. Health care facilities around the country and the world were being overwhelmed by COVID-19. As previously described, health care staff were disproportionately impacted by COVID-19. Additionally, patients in health care facilities were at substantial risk of exposure and infection with COVID-19 despite precautionary measures that were taken to reduce the risk of transmission in health care settings. Often, patients in health care settings were at increased risk of severe COVID-19 because of underlying health conditions and age.

As of September 2021, were mandatory COVID-19 vaccine policies a critical protective action for health care institutions to protect patients and staff?

As of September 2021, mandatory COVID-19 vaccine policies were a critical protective action for health care institutions to protect patients and staff for the following reasons:

1. COVID-19 posed a substantial threat to patients and staff in health care institutions (previously described);
2. COVID-19 vaccines provided a high level of protection against contracting COVID-19 and reducing transmission of COVID-19 (previously described); and
3. Mandatory vaccination policies for influenza vaccines in health care settings have been demonstrated to be necessary to achieve high levels of vaccine coverage (voluntary policies even coupled with free access to vaccines and education did not achieve very high levels of vaccine coverage).

Did anticipation of the upcoming flu season justify rollout of mandatory COVID- 19 vaccine policy in as of September 2021?

In 2020 we wrote a commentary in the Journal of the American Medical Association (JAMA) warning of the potential dangers of COVID-19 and influenza: The Dual Epidemics of COVID-19 and Influenza - Vaccine Acceptance, Coverage, and Mandates.[30] Both **influenza and COVID-19** are unpredictable viruses with the potential to mutate, cause similar symptoms, strain the health care system, are often transmitted in a health care setting (particularly to high risk patients), and are preventable by vaccination. As we stated in this article:

> The health system, and wider society, must prepare for the likelihood of co-epidemics of COVID-19 and influenza… The nation's goal should be to attain high influenza vaccine coverage, including near-universal coverage among health care personnel and other high-risk groups for COVID-19… The CDC prioritizes high-risk groups and their contacts/caregivers for influenza vaccinations. Health care personnel are exposed to pathogens that can be transmitted to and from patients, even if staff are not directly involved in patient care. In 2018-2019, vaccine coverage among health care personnel reached 81.1%, similar to previous seasons (77.3%-79.0%).[6] Given the heightened importance of health care worker

[30] Lawrence Gostin and Daniel A Salmon. The Dual Epidemics of COVID-19 and InfluenzaVaccine Acceptance, Coverage, and Mandates JAMA. 2020;324(4):335-336.

> and patient safety during the co-epidemics of COVID-19 and influenza, higher vaccine coverage should be a national priority… Given the high risks, health workers would gain high priority for COVID-19 vaccination. Strong incentives should be in place, including laws requiring health facilities to routinely offer both influenza and COIVID-19 vaccines.

Fortunately, 2020-21 was a mild influenza season in the United States and globally most likely because of social distancing, masks and other control measures for COVID-19. However, many of these measures were being relaxed in 2021 and there were widespread concerns that 2021-22 would be a particularly bad influenza season. Additionally, a mild 2019-20 influenza season meant that more people would be susceptible to influenza in the 2020-21 influenza season as influenza in the previous season can sometimes provide protection in the current year (depending on the strains of influenza that are circulating).

Mandatory influenza vaccine policies are very important for healthcare institutions and directly relate to mandatory COVID-19 vaccine policies. Exposure to influenza in health care settings is an occupational hazard. Asymptomatic and health care workers who come to work ill (including the day before symptoms become apparent and the person is infectious) can transmit influenza to patients. Likewise, patients may be asymptomatic and transmitting influenza, including to unvaccinated healthcare workers and other patients. There are a broad range of strategies to reduce the risk of influenza among health care workers and protect patients who come into contact with such personnel. Strategies to reduce the risk of influenza in healthcare institutions include offering education and free, on-site vaccination, implementation of hand and respiratory hygiene and cough etiquette, screening and isolation of healthcare workers and patients with acute respiratory infections, and other prevention measures.[31]

Influenza vaccination is the most effective strategy to protect healthcare workers from contracting influenza and transmitting it to their patients. Vaccination of healthcare workers has been shown to be very effective, with minimal adverse effects, and shown to reduce patient mortality. [32] Despite considerable efforts at the Federal level and among states, with strong support from medical associations, influenza vaccination coverage among healthcare workers remains suboptimal.

Many healthcare institutions require influenza vaccination among their workers to protect their employees and the patients they care for. The Society for Healthcare Epidemiology of America (SHEA) strongly endorses mandatory vaccination of healthcare workers to protect against influenza, as can be seen in their most recent policy position on this topic:

> SHEA views influenza vaccination of HCP as a *core patient and HCP safety practice* with which noncompliance should not be tolerated. It is the professional and ethical responsibility of HCP and the institutions within which they work to prevent the spread of infectious pathogens to their patients through evidence-based infection prevention practices, including influenza vaccination. *Therefore, for the safety of both patients and*

[31] CDC. Prevention Strategies for Seasonal Influenza in Healthcare Settings. [cited 2011 17 November]; Available from: http://www.cdc.gov/flu/professionals/infectioncontrol/healthcaresettings.htm. accessed 04/02/23.
[32] Burls A, Jordan R, Barton P et al. Vaccinating healthcare workers against influenza to protect the vulnerable – is it. A good use of healthcare resources? A systematic review of the evidence and an economic evaluation. Vaccine. 2006. May 8; 24(19): 4212-21.

HCP, SHEA endorses a policy in which annual influenza vaccination is a condition of both initial and continued HCP employment and/or professional privileges. [33]

Many professional medical and public health associations also support mandatory influenza vaccination of healthcare workers, including the American Academy of Family Physicians, the American Academy of Pediatrics, the American College of Physicians, the American Hospital Association, the American Medical Directors Association, the American Nurses Association, the American Public Health Association, the Association for Professionals in Infection Control and Epidemiology, the Infectious Disease Society of America, the National Association of County and City Health Officials, National Patient Safety Foundation, and others.[34]

This experience with influenza vaccine mandates in health care settings is directly applicable to COVID-19 mandates in health care settings. As with influenza, COVID-19 exposure in health care settings is an occupational hazard. Asymptomatic and health care workers who come to work ill (including the day before symptoms become apparent and the person is infectious) can transmit COVID-19 to patients. Likewise, patients may be asymptomatic and transmitting COVID-19, including to unvaccinated healthcare workers and other patients. Voluntary programs for COVID-19 vaccine even coupled with access and education, as is the case with influenza, were unlikely to adequately in reaching very high levels of vaccine coverage necessary for protecting health care workers and patients. For example, we conducted a survey in late 2020 before the vaccines were available at SUNY Upstate Medical University in Syracuse, NY, the only academic medical center in Central New York and the region's largest employer with 9,565 employees.[35] We found that 57.5% of individuals expressed intent to receive COVID-19 vaccine, including 80.4% of physicians and scientists. Nearly half or more of nurses, Master's level clinicians, allied health professionals, and ancillary service personnel were not sure whether the vaccine will work and protect them from COVID-19; slightly lower but similar levels of uncertainty were expressed by the same groups about vaccine safety, and nearly a third of each group was unsure whether they would take a vaccine for COVID-19 if offered for free. The attitudes and concerns of nurses were very similar to those of the general public at the time. We conducted a follow-up survey in this health care system between 21 February and 19 March 2021 and found that 87.7% of respondents had already received a COVID-19 vaccine or planned to get vaccinated.[36] Physicians and scientists showed the highest acceptance rate (97.3%), whereas staff in ancillary services showed the lowest acceptance rate (79.9%). These levels of COVID-19 vaccine coverage are too low, leading New

[33] Revised SHEA position paper: influenza vaccination of healthcare personnel. Infection Control and Hospital Epidemiology. Oct 2010. 31(10); 987-995.

[34] See https://www.immunize.org/honor-roll/influenza-mandates/ for list of these organizations that have policy positions supporting mandatory influenza vaccination for healthcare workers, including links to these policy statements. Accessed 04/02/20.

[35] Jana Shaw, Telisa Steward, Kathryn Anderson, Samantha Hanley, Stephen Thomas, Daniel Salmon, Christopher Morley. Assessment of U.S. health care personnel (HCP) attitudes towards COVID-19 vaccination in a large university health care system. Clin Infect Dis. 2021 Jan 25.

[36] Jana Shaw, Samantha Hanley, Telisa Steward, Daniel Salmon, Christin Ortiz, Paula Trief, Elizabeth Reddy, Christopher Morley, Stephen Thomas, Kathryn Anderson. Healthcare Personnel (HCP) Attitudes About Coronavirus Disease 2019 (COVID-19) Vaccination After Emergency Use Authorization. Clin Infect Dis. 2022 Aug 24;75(1):e814-e821.

York to require vaccination of healthcare workers in September of 2021 and experiencing a 10% increase in vaccine coverage within a week.[37]

Many health care systems were finding voluntary programs for COVID-19 vaccination in health care settings to be insufficient and were thus turning to mandatory programs. According to the COVID States Project, as of July, 2021, 27% of healthcare workers were unvaccinated and 15% were vaccine resistant, leading the authors to conclude that "absent mandates, most of the currently unvaccinated health care workers will remain unvaccinated, potentially fueling outbreaks in health care facilities."[38] A joint statement by nearly 88 major medical organizations and associations called for mandatory vaccination of healthcare workers, including the American Hospital Association, the American Medical Association, the American College of Physicians, the American Academy of Family Physicians, and the American Public Health Association (see below).[38,39] In August, 2021, the Department of Veterans Affairs announced that all employees and staff at VA facilities had to be vaccinated for COVID-19.[40] On September 9, 2021, President Biden announced a requirement for all health care workers working in a settings that receive Medicare or Medicaid reimbursement to receive COVID-19 vaccines.[41]

[37] Forbes. Covid-19 Vaccine Mandates Are Working—Here's The Proof https://www.forbes.com/sites/tommybeer/2021/10/04/covid-19-vaccine-mandates-are-working-heres-the-proof/?sh=8555e4b23058 accessed 03/30/23

[38] Lazer David, et al. The COVID States Project #62: COVID-19 vaccine attitudes among healthcare workers. The COVID States Project. Aug 18, 2021

[39] Joint Statement in Support of COVID-19 Vaccine Mandates for All Workers in Health and Long-Term Care. https://assets.acponline.org/acp_policy/statements/joint_statement_covid_vaccine_mandate_2021.pdf accessed 03/30/23

[40] US Department of Veteran Affairs. VA mandates COVID-19 vaccines among its medical employees including VHA facilities staff. https://www.va.gov/opa/pressrel/pressrelease.cfm?id=5696 accessed 03/30/23

[41] The White House. Remarks by President Biden on Fighting the COVID-19 Pandemic https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/ accessed 03/30/23

Joint Statement in Support of COVID-19 Vaccine Mandates for All Workers in Health and Long-Term Care

Due to the recent COVID-19 surge and the availability of safe and effective vaccines, our health care organizations and societies advocate that all health care and long-term care employers require their workers to receive the COVID-19 vaccine. This is the logical fulfillment of the ethical commitment of all health care workers to put patients as well as residents of long-term care facilities first and take all steps necessary to ensure their health and well-being.

Because of highly contagious variants, including the Delta variant, and significant numbers of unvaccinated people, COVID-19 cases, hospitalizations and deaths are once again rising throughout the United States.[1] Vaccination is the primary way to put the pandemic behind us and avoid the return of stringent public health measures.

Unfortunately, many health care and long-term care personnel remain unvaccinated. As we move towards full FDA approval of the currently available vaccines, all health care workers should get vaccinated for their own health, and to protect their colleagues, families, residents of long-term care facilities and patients. This is especially necessary to protect those who are vulnerable, including unvaccinated children and the immunocompromised. Indeed, this is why many health care and long-term care organizations already require vaccinations for influenza, hepatitis B, and pertussis.

We call for all health care and long-term care employers to require their employees to be vaccinated against COVID-19.

We stand with the growing number of experts and institutions that support the requirement for universal vaccination of health workers.[2,3] While we recognize some workers cannot be vaccinated because of identified medical reasons and should be exempted from a mandate, they constitute a small minority of all workers. Employers should consider any applicable state laws on a case-by-case basis.

Existing COVID-19 vaccine mandates have proven effective.[4,5] Simultaneously, we recognize the historical mistrust of health care institutions, including among many in our own health care workforce. We must continue to address workers' concerns, engage with marginalized populations, and work with trusted messengers to improve vaccine acceptance.

As the health care community leads the way in requiring vaccines for our employees, we hope all other employers across the country will follow our lead and implement effective policies to encourage vaccination. The health and safety of U.S. workers, families, communities, and the nation depends on it.

SIGNATORIES (Listed Alphabetically)

Academy of Managed Care Pharmacy (AMCP)
American Academy of Ambulatory Care Nursing (AAACN)
American Academy of Allergy, Asthma & Immunology (AAAAI)
American Academy of Child and Adolescent Psychiatry (AACAP)
American Academy of Emergency Medicine (AAEM)
American Academy of Family Physicians (AAFP)
American Academy of Nursing (AAN)
American Academy of Ophthalmology (AAO)
American Academy of PAs (AAPA)
American Academy of Pediatrics (AAP)
American Association for Respiratory Care (AARC)
American Association of Clinical Endocrinology (AACE)
American Association of Colleges of Pharmacy (AACP)
American Association of Neuroscience Nurses (AANN)
American College of Allergy, Asthma and Immunology (ACAAI)
American College of Clinical Engineering (ACCE)
American College of Clinical Pharmacy (ACCP)
American College of Emergency Physicians (ACEP)
American College of Gastroenterology (ACG)
American College of Medical Genetics and Genomics (ACMG)
American College of Medical Toxicology (ACMT)
American College of Mohs Surgery (ACMS)
American College of Osteopathic Family Physicians (ACOFP)
American College of Physicians (ACP)
American College of Preventive Medicine (ACPM)
American College of Surgeons (ACS)
American Epilepsy Society (AES)
American Geriatrics Society (AGS)
American Medical Association (AMA)
American Medical Women's Association (AMWA)
American Nurses Association (ANA)
American Occupational Therapy Association (AOTA)
American Osteopathic Association (AOA)
American Pharmacists Association (APhA)
American Psychiatric Association (APA)
American Psychological Association (APA)
American Public Health Association (APHA)
American Society for Clinical Pathology (ASCP)
American Society for Radiation Oncology (ASTRO)
American Society for Transplantation and Cellular Therapy (ASTCT)
American Society of Health-System Pharmacists (ASHP)
American Society of Hematology (ASH)
American Society of Nephrology (ASN)
American Thoracic Society (ATS)
Association for Clinical Oncology (ASCO)
Association for Professionals in Infection Control and Epidemiology (APIC)
Association of Academic Health Centers (AAHC)
Association of American Medical Colleges (AAMC)
Association of Pediatric Hematology/Oncology Nurses (APHON)
Association of Rehabilitation Nurses (ARN)
Connecticut Nurses Association (CNA)
Council of Medical Specialty Societies (CMSS)
Delaware Nurses Association (DNA)
Emergency Medicine Residents' Association (EMRA)
Hematology/Oncology Pharmacy Association (HOPA)
HIV Medicine Association
Illinois Pharmacists Association (IPhA)
Infectious Diseases Society of America (IDSA)
LeadingAge
Medical Society of Virginia (MSV)
Missouri State Medical Association (MSMA)
National Association of Indian Nurses of America (NAINA)
National Association of Pediatric Nurse Practitioners (NAPNAP)
National Council of Asian Pacific Islander Physicians (NCAPIP)
National Council of State Boards of Nursing (NCSBN)
National Hispanic Medical Association (NHMA)
National League for Nursing (NLN)
National Medical Association (NMA)
National Pharmaceutical Association (NPhA)
New Hampshire Nurses Association (NHNA)
New Mexico Medical Society (NMMS)
Nurses Who Vaccinate (NWV)
Organization for Associate Degree Nursing (OADN)
Pediatric Infectious Diseases Society (PIDS)
Philippine Nurses Association of America, Inc (PNAA)
Society of Gynecologic Oncology (SGO)
Society for Healthcare Epidemiology of America (SHEA)
Society of Hospital Medicine (SHM)
Society for Immunotherapy of Cancer (SITC)
Society of Infectious Diseases Pharmacists (SIDP)
Society of Interventional Radiology (SIR)
Society of Nuclear Medicine & Molecular Imaging (SNMMI)
South Carolina Nurses Association (SCNA)
Texas Nurses Association (TNA)
The John A. Hartford Foundation
Transcultural Nursing Society (TCNS)
Virgin Islands State Nurses Association (VISNA)
Wound, Ostomy, and Continence Nurses Society (WOCN)

1. Centers for Disease Control and Prevention. Covid Data Tracker Weekly Review. July 16, 2021. https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html [Accessed 22 July 2021].
2. Weber, D., Al-Tawfiq, J., Babcock, H., Bryant, K., Drees, M., Elshaboury, R., et al. (2021). Multisociety Statement on COVID-19 Vaccination as a Condition of Employment for Healthcare Personnel. Infection Control & Hospital Epidemiology, 1-46. doi:10.1017/ice.2021.322
3. American Hospital Association. AHA Policy Statement on Mandatory COVID-19 Vaccination of Health Care Personnel. July 21, 2021. https://www.aha.org/public-comments/2021-07-21-aha-policy-statement-mandatory-covid-19-vaccination-health-care
4. Bacon J. 'Condition of employment': Hospitals in DC, across the nation follow Houston Methodist in requiring vaccination for workers. *USA Today*. Available from: https://www.aha.org/public-comments/2021-07-21-aha-policy-statement-mandatory-covid-19-vaccination-health-care [Accessed 22 July 2021].
5. Paulin E. More Nursing Homes Are Requiring Staff COVID-19 Vaccinations. *AARP*. Available from: https://www.aarp.org/caregiving/health/info-2021/nursing-homes-covid-vaccine-mandate.html [Accessed 22 July 2021].

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Did mandatory COVID-19 vaccine policies pose risk that health care workers would choose to leave job rather than get vaccinated?

There was the potential that some health care workers would choose to leave their job rather than get vaccinated. Undoubtedly, some health care workers did leave their job when COVID-19 vaccines were required. Some of this risk of health care workers leaving their jobs because of COVID-19 mandates could be mitigated by making vaccine readily available free of charge and through vaccine education. New York state's COVID-19 vaccine mandate resulted in about 34,000 health workers losing jobs or being placed on leave, reflecting a reduction of 3.5% of the workforce.[42] A COVID-19 mandate for health care workers in Colorado resulted in 1.8% of health care workers leaving or losing their jobs because of a COVID-19 mandate.[43]

How did mandatory COVID-19 vaccine policies impact vaccine hesitancy?

Mandatory COVID-19 policies likely had a mixed impact on vaccine hesitancy. For those who strongly held views against vaccination, mandatory policies likely further solidified those beliefs. The vast majority of people in favor of vaccination would likely be vaccinated absent such policies, particularly as COVID-19 vaccines were free and readily available. For those in the middle, often referred to as "fence sitters", mandatory COVID-19 vaccines would likely push some towards the decision to vaccinate. Additionally, mandatory COVID-19 vaccine policies also create a social norm to vaccinate, having a broader indirect impact on vaccine acceptance.

What was the impact of medical and religious exemption requests on health care institutions?

What were the clinical contraindications to receiving the COVID vaccine?

There are two contraindications for COVID-19 vaccines: 1) History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine; or 2) History of a known diagnosed allergy to a component of the COVID-19 vaccine.[44]

How did non-medical vaccine exemption requests impact the efficacy of vaccine requirements and patient safety?

Unvaccinated persons (those with non-medical exemptions) are at increased risk of contracting disease and transmitting disease to others who cannot be vaccinated (because of medical contraindications), are too young to be vaccinated, or who are vaccinated but the vaccine did not work for them (no vaccine is 100% effective). The impact of non-medical exemptions has been extensively studied among children for pertussis and measles, through the epidemiological

[42] lohud. Remarks by President Biden on Fighting the COVID-19 Pandemic. https://www.lohud.com/story/news/coronavirus/2021/10/14/how-many-health-workers-lost-jobs-due-ny-vaccine-mandate/8449413002/ accessed 03/30/23

[43] The Colorado Sun. Did Colorado's COVID vaccine mandate for health care workers hurt hospital staffing? It's complicated. https://coloradosun.com/2021/11/17/health-care-worker-vaccination-mandate-staffing/ accessed 03/30/23

[44] Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#covid-vaccines accessed 03/30/23

principles apply to influenza vaccine and non-medical exemptions among healthcare workers. Children who have non-medical exemptions are 22-35 times more likely to contract measles and 6 times more likely to contract pertussis than vaccinated children.[45,46] In addition to this individual risk, exempt persons also increase the risk to others. Studies we have conducted demonstrate that communities with higher rates of non-medical exemptions are at increased risk of pertussis outbreaks.[45,46,47] We also found that states that had easier non-medical exemptions processes for granting exemptions had higher rates of non-medical exemptions and higher rates of pertussis.[48,49] Measles also highlights the community risks of vaccine refusal.[50] Measles has been eliminated in the United States because of sustained high coverage of a very safe and effective vaccine. However, there are communities in the United States with high rates of vaccine refusal and measles is still circulating in many parts of the world. As a result, measles is introduced into these communities with high rates of vaccine refusal – clustered socially or geographically – resulting in outbreaks of measles.[51]

An outbreak originating in Disneyland in 2015 caught the most national attention though there have been similar outbreaks in the Somali community in Minnesota and orthodox Jewish community in New York. As a result, the United States almost lost its "elimination status" in 2009, the same year that the World Health Organization declared vaccine hesitancy a top 10 global health threat. Several states (California, New York, Maine and Washington) have consequently eliminated their non-medical exemptions (Washington only eliminated non-medical exemptions for the MMR vaccine). There was recently a case of paralytic polio in the same orthodox Jewish community in New York which had the measles outbreak. This single case of polio indicates there are likely thousands of cases of asymptomatic polio in the community given the often asymptomatic nature of polio. Sewage samples testing positive for polio support this.

These studies have been focused on children because every state has laws requiring vaccination for school entry. These studies have focused on measles and pertussis because the epidemiology of the diseases makes them well suited for such studies. However, the findings from these studies are very generalizable to non-medical exemptions to COVID-19 vaccine requirements for healthcare workers given the nature of infectious diseases and the impact of unvaccinated persons with non-medical exemptions. In fact, the impact of non-medical exemptions for COVID-19 vaccine among

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[45] Salmon DA, Haber M, Gangarosa EJ, Phillips L, Smith N, Chen RT. Health consequences of religious and philosophical exemptions from immunization laws: individual and societal risks of measles. JAMA. 1999 July 7; 282(1): 47-53.

[46] Feikin DR, Lezotte DC, Hamman RF, Salmon DA**,** Chen RT, Hoffman RE. Individual and community risks of measles and pertussis associated with personal exemptions to immunizations. JAMA. 2000 Dec. 27; 284(24): 3145-3150.

[47] Atwell JE, Van Otterloo J, Zipprich J, Winter K, Harriman K, Salmon DA, Halsey NA, Omer SB. Nonmedical vaccine exemptions and pertussis in California, 2010. Pediatrics. 2013 Oct;132(4):624-30.

[48] Rota JS, Salmon DA, Rodewald LE, Chen RT, Hibbs BF, Gangarosa EJ. Processes for obtaining nonmedical exemptions to state immunization laws. AJPH. April 2000; 91: 645-8.

[49] Omer SB, Pan WK, Halsey NA, Stokely S, Moulton LH, Navar AM, Salmon DA. Nonmedical Exemptions to School Immunization Requirements: Secular Trends and Association of State Policies with Pertussis Incidence. JAMA. 2006 Oct 11; 296(14):1757-63.

[50] Salmon DA, Dudley MZ*, Glanz JM, Omer SB. Vaccine hesitancy: Causes, consequences, and a call to action. Co-Published. Vaccine & Am J Prev Med. 2015 Nov 23; Suppl 4:D66-71.

[51] Phadke VK. Bednarczyk RA, Salmon DA, Omer SB. Association between Vaccine Refusal and Vaccine Preventable Diseases in the United States: A Focus on Measles and Pertussis. JAMA. 2016 Mar; 315(11): 1149-58.

healthcare workers would be much higher than in the case with childhood vaccine because healthcare workers regularly come into contact with patients that are at high risk COVID-19 complications and death.

How did exemptions impact the operations of the health care institutions?

Exemptions to vaccine mandates had a substantial impact on the operations of the health care institutions. Health care institutions had to grant medical exemptions based upon valid medial contraindications (previously discussed). Health care institutions which granted religious exemptions needed to develop a process by which religious exemption requests would be submitted and criteria for granting or denying requests. As discussed, it has been shown that exemptions that are easily granted are associated with higher rates of exemptions and disease in the context of childhood vaccine requirements. Allowing all exemption requests to be granted would have likely resulted in a large number of exemptions, and, as previously described, a larger number of religious exemptions would result in a greater risk of COVID-19 disease transmission and outbreaks adversely impacting other health care staff, patients, and the capacity of the health care system to operate. One can reasonably conclude that such additional exemptions would be geographically clustered, increasing their impact, given COVID-19 vaccine hesitancy has been shown to geographically cluster and health care workers tend to live in the communities in which they work.

Did health care institutions have a responsibility to patients and staff to establish and implement a process for evaluating exemption requests rather than simply rubber-stamping requests?

Health care institutions had a responsibility to limit religious exemptions to those with sincerely held beliefs that precluded vaccination in order to protect their staff and patients. As previously described, individuals who are granted exemptions to immunization requirements are at increased risk of contracting and transmitting vaccine preventable diseases. The greater the number of religious exemptions the higher the risk of COVID-19 infections and transmission. Medical exemptions, based upon valid medical contraindications, are necessary and rare. Religious exemptions represent an effort to accommodate the religious views of those impacted by mandatory policies. However, granting too many exemptions can undermine the impact of the mandatory policy and lead to disease outbreaks. It is for this reason that several states have recently eliminated non-medical exemptions to school immunization requirements. Ensuring that sincerely held religious beliefs that prevent vaccination are granted exemptions but restricting exemptions to those with sincerely held religious beliefs limits the adverse impact of exemptions on outbreaks of disease while preserving this exemption option for those who with the sincerely held religious beliefs.

Do exemptions from a mandatory vaccination policy undermine an organization's ability to inhibit the spread of a serious communicable disease?

Exemptions from mandatory vaccination policy have the potential to undermine an organization's ability to inhibit the spread of a serious communication disease. Whether or not this potential is realized and the extent to which exemptions undermine the control of vaccine preventable

diseases depends on the frequency of exemptions and the extent to which they are geographically clustered.

How effective were alternative infection control strategies (masking, testing, social distancing) in health care institutions?

In addition to vaccination, alternative infection control strategies such as masking, testing and social distancing had an impact in health care institutions. However, each of these strategies had limitations and the most effective policy to control COVID-19 in health care settings was a compressive approach where strategies were combined or layered.

The use of masks in health care settings to prevent COVID-19 vaccine was based on what was known regarding mask wearing in health care settings to control influenza. Wearing a mask has a clear benefit in reducing the acquisition and transmission of influenza. Two studies have shown that surgical masks are similar to some types of respirators in protecting healthcare workers from acquiring influenza.[52,53] However, wearing a surgical mask when treating patients in lieu of mandatory vaccination is problematic for many reasons. First and foremost, surgical masks do not work as well as vaccination which is why the Centers for Disease Control and Prevention (CDC) considers influenza vaccination the first and best way to prevent influenza. Additionally, implementing a surgical mask policy in lieu of vaccination is problematic. A study of health care workers at 12 hospitals found that the SARS-CoV-2 test positivity rate among health care workers decreased from 14.7% to 11.5% during a 3-week period after implementation of universal masking.[54] Such a program requires oversight to ensure compliance. Doing so would be very difficult, particularly if only for employees who have forgone vaccination. The healthcare institution would need to know who has a non-medical exemption and then develop a program that would target them to make sure they consistently wear the mask. This would be a difficult and expensive program to implement and poor compliance would further enhance the risk of influenza acquisition and transmission.

Regular testing for COVID-19 allows for the identification of persons who have active disease. However, there are limitations to this approach. First, available COVID-19 tests are imperfect with the potential for both false positives and false negatives. Additionally, by September of 2021, it had been well established that people could transmit COVID-19 before becoming symptomatic and among asymptomatic cases. As a consequence, even daily COVID-19 testing would not identify people as soon as they became infectious. In the time between when a person first became infectious and when the test was taken there was risk that the person would infect others.

Social distancing also had the potential to reduce transmission of COVID-19 in health care settings. Most health care facilities attempted to isolate COVID-19 cases. However, staff often

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[52] Johnson DF, Druce JD, Birch C, Grayson ML. A quantitative assessment of the efficacy of surgical and N95 masks to filter influenza virus in patients with acute influenza infection. Clin Infect Dis 2009;49(2):275–277.
[53] Aiello AE, Murray GF, Perez V, et al. Mask use, hand hygiene, and seasonal influenza-like illness among young adults: a randomized intervention trial. J Infect Dis;201(4):491–498.
[54] Wang X, Ferro EG, Zhou G, et al. Association between universal masking in a health care system and SARS-CoV-2 positivity among health care workers. *JAMA*. 2020;324(7):703.

needed to work with both COVID-19 and other patients, allowing opportunities for transmission. Additionally, staff and patients may be asymptomatically transmitting COVID-19. Reducing the density of the population (distance between persons or less people permitted in a defined space) could also reduce COVID-19 transmission. However, this is very difficult to operationalize in a health care setting. Health care workers who work from home some of the time, even with limited interactions with patients and coworkers, can still contract and transmit of COVID-19 when in the health care setting.

Each of these approaches – vaccination, masks, testing, social distancing – all have the potential to reduce disease transmission but are all imperfect by themselves. While the vaccines were shown to have very high efficacy, they are imperfect and some people who are vaccinated will still contract and transmit disease. Similarly, but to a lesser extent, each of these other strategies have an impact. However, they are also imperfect. The most effective approach to reducing transmission of COVID-19 in a health care setting is to require all these approaches, thus layering protection.

Anti-vaccine movement's impact on mandatory vaccine policies

Was there an anti-vax movement that impacted COVID-19 vaccine hesitancy in 2021?

Anti-vaccine groups have existed as long as we have had vaccines, dating back to the Smallpox vaccine created by Edward Jenner in the late 18th century. Over time, the issues have evolved through many of the central arguments have remained the same. In the 1970's and 1980's, the antivaccine movement in the United States and many developed countries were focused on the whole cell pertussis vaccine. Japan, the UK and Sweden experiences substantial drops in vaccination coverage and resurgence of pertussis. In the 1990's, concerns raised that the MMR vaccine caused autism were championed by anti-vaccine groups and led to a major resurgence of measles across Europe with introductions of measles into the United States. In 2019, just before the COVID-19 pandemic, the World Health Organization declared vaccine hesitancy a top 10 global threat. While the issues have evolved, the underlying arguments of the anti-vaccine movement have been remarkably stable over time, as described by Wolfe and Sharpe[55]:

> *19th century*—Typical membership:
> 1. Those who feel smallpox vaccination is ineffective
> 2. Persons who believed their relatives had suffered injury or death due to vaccination
> 3. Persons opposed to compulsory vaccination as an infringement of basic human rights
> 4. Proponents of alternative medical practice and theory, especially homoeopaths. Herbalists, chiropractors, and hydropaths
>
> *20th century*—Typical membership:
> 1. Those who feel that some or all vaccinations are ineffective or unsafe
> 2. Persons who believe their relatives had suffered injury or death due to vaccination
> 3. Persons opposed to compulsory vaccination as an infringement of basic human rights

[55] Robert Wolfe and Lisa Sharp, Anti-vaccinationists past and present. BMJ. 2002 Aug 24; 325(7361): 430–432.

4. Proponents of alternative medical practice and theory, such as homoeopathy, herbal therapy, and chiropractic

The anti-vaccine movement was extremely well positioned (and funded) when the COVID-19 pandemic struck. Anti-vaccine groups were able to build relationships with and expand their influence by persons and groups who perceived the public health and government response to COVID-19 was infringing on their personal freedoms. Mask wearing quickly became controversial as some people objected to being told to wear a mask. Social distancing and the closing of some business were even more controversial. There were clear political divides in the United States COVID-19 response, with political affiliation becoming one of the best predictors of COVID-19 vaccination.[56]

As described in a Lancet Commission report (in which I am a co-author)[57]:

> Over the past two decades, anti-vaccine activism in the USA has evolved from a fringe subculture into an increasingly well organised, networked movement with important repercussions for public health. The COVID-19 pandemic has exacerbated this evolution and magnified the reach of vaccine misinformation. Anti-vaccine activists, who for many years spoke primarily to niche communities hesitant about childhood vaccinations, have used traditional and social media to amplify vaccine-related mistruths about COVID-19 vaccines while also targeting historically marginalised racial and ethnic communities. These efforts contributed to COVID-19 vaccine hesitancy and expanded the movement, with early indications suggesting that this hesitancy could now also be increasing hesitancy that existed pre-pandemic towards other vaccines.

Thus, Anti-vaccine groups were able to capitalize on the controversies around COVID-19 and COVID-19 control strategies including but limited to vaccination. There is no question that anti-vaccine groups had an impact on COVID-19 vaccine hesitancy.

What is the impact of the anti-vaccine movement on mandatory vaccine policies?

There has been a very strong and concerted effort by the anti-vaccine movement to loosen state laws requiring vaccination of school children, particularly over the past decade. The reasons behind this are multifactorial. First and foremost, anti-vaccine groups have become fairly sophisticated in how they present themselves and frame their arguments. They have learned over the past few decades that they are not perceived well – by the media, politicians or much of the public – if they present themselves as being against vaccines. Thus, they tend to present

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[56] Matthew Z Dudley, Benjamin Schwartz, Janesse Brewer, Lilly Kan, Roger Bernier, Jennifer E Gerber, Haley Budigan Ni, Tina M Proveaux, Rajiv N Rimal, Daniel A Salmon. COVID-19 Vaccination Status, Attitudes, and Values among US Adults in September 2021. J Clin Med. 2022 Jun 28;11(13):3734.

[57] Richard M Carpiano, Timothy Callaghan, Renee DiResta, Noel T Brewer, Chelsea Clinton, Alison P Galvani, Rekha Lakshmanan, Wendy E Parmet, Saad B Omer, Alison M Buttenheim, Regina M Benjamin, Arthur Caplan, Jad A Elharake, Lisa C Flowers, Yvonne A Maldonado, Michelle M Mello, Douglas J Opel, Daniel A Salmon, Jason L Schwartz, Joshua M Sharfstein, Peter J Hotez. Confronting the evolution and expansion of anti-vaccine activism in the USA in the COVID-19 era. Lancet. 2023 Mar 18;401(10380):967-970.

themselves as being advocates for informed choice and the safety of vaccines. This is a very effective approach to open doors and influence policy, discourse and the thinking and decisions of the public. Central to this argument of informed choice is the ability of persons to claim non-medical exemptions. Additionally, because all school immunization requirements are state rather than federal laws this allows anti-vaccine groups to focus their efforts on individual states where they are more likely to sway local legislators and manipulate public opinion than they could achieve at the federal level. In many states, anti-vaccine groups have established state chapters or organizations who find state legislators who are sympathetic to their views and willing to propose legislation expanding non-medical exemptions. Anti-vaccine groups have rallied opposition to mandatory COVID-19 vaccine policies.

Stem cells: Some individuals who challenged mandatory COVID vaccine policies raised religious objections based on stem cell use in testing/development of vaccines

Which stem cell lines were used in testing the COVID-19 vaccines available in 2021?

Some COVID-19 vaccines used cells, either in development or in manufacturing, originally isolated from fetal tissues derived from an aborted fetus. The fetal cell lines being used to test or manufacture the COVID-19 vaccines are from two sources[58]:

- HEK-293: A kidney cell line that was isolated from a fetus in 1973
- PER.C6: A retinal cell line that was isolated from a fetus in 1985

In neither of these cases was an abortion done for the purposes of harvesting a fetal cell line. These cell lines are used in a in vaccine and other drug development as well as manufacturing of some drugs and vaccines because they have been extremely well characterized over many decades, providing advantages over other cell lines where less in known about them.[59]

Fetal cell lines were used in the early in the development of mRNA vaccine technology.

The Pfizer and Moderna mRNA COVID-19 vaccines produced do not use any fetal cell cultures to manufacture the vaccine.

The Johnson & Johnson COVID-19 vaccine uses fetal cell cultures (PER.C6) to manufacture the vaccine.[60]

Other medicines for which stem cells were used in testing

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[58] Richard K. Zimmerman. Helping patients with ethical concerns about COVID-19 vaccines in light of fetal cell lines used in some COVID-19 vaccines. Vaccine. 2021 Jul 13; 39(31): 4242–4244. Published online 2021 Jun 15. doi: 10.1016/j.vaccine.2021.06.027

[59] John Grabenstein. What the World's religions teach, applied to vaccines and immune globulins. Vaccine. Volume 31, Issue 16, 12 April 2013, Pages 2011-2023.

[60] Janssen. https://www.janssenscience.com/products/janssen-covid-19-vaccine/medical-content/janssen-covid-19-vaccine-janssen-covid-19-vaccine-no-presence-of-fetal-tissue-or-human-cells accessed 04/04/23

HEK293 cells are one of the most widely used cell lines in research because they are easy to manipulate and are immortal (can be grown and replicated indefinitely). The following commonly used drugs (not comprehensive) have been tested, developed or manufactured using fetal cell lines.[61]

Common over the counter drugs tested on HEK-293 cells or derivative cell lines.

1. Tylenol / Acetaminophen
2. Advil / Motrin / Ibuprofen
3. Aspirin / Acetylsalicylic Acid (ASA)
4. Aleve / Naproxen
5. Pseudoephedrine / Sudafed / / SudoGest, Suphedrine
6. Diphenhydramine / Benadryl
7. Loratadine / Claritin
8. Dextromethorphan / Delsym / Robafen Cough / Robitussin
9. Guaifenesin / Mucinex
10. Tums / Calcium Carbonate
11. Maalox / Aluminum Hydroxide and Magnesium Hydroxide
12. Docusate / Colace / Ex-Lax Stool Softener
13. Senna Glycoside / Sennoside / Senna / Ex-Lax / Senokot
14. Pepto-Bismol / Bismuth Subsalicylate
15. Phenylephrine / Preparation H / Vazculep / Suphedrine PE
16. Mepyramine / Pyrilamine
17. Lidocaine / Lidoderm / Recticare

Common prescription drugs tested on HEK-293 cells or derivative cell lines.

1. Levothyroxine / Synthroid / Tirosint / Levoxyl
2. Atorvastatin / Lipitor
3. Amlodipine / Norvasc
4. Metoprolol / Toprol XL / Lopressor
5. Omeprazole / Prilosec OTC / Zegerid OTC / OmePPi
6. Losartan / Cozaar
7. Albuterol / Salbutamol / ProAir / Ventolin
8. Enbrel / Etanercept
9. Azithromycin / Zithromax
10. Hydroxychloroquine / Plaquenil
11. Remdesivir / Veklury
12. Dapagliflozin / Farxiga / Ipragliflozin / Suglat / Enavogliflozin / Jardiance
13. Ivermectin / Stromectol
14. Metformin / Glucophage / Riomet / Glumetza

[61] Commonwealth Journal. April 4, 2023. https://www.somerset-kentucky.com/opinion/letters_to_the_editor/there-are-no-aborted-fetal-cells-in-vaccines/article_14809887-84f7-58a4-bb4c-76bc29724d8a.html accessed 04/04/23

When was Novavax available in the United States?

The U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the Novavax COVID-19 Vaccine on July 13, 2022.[62]

Did the manufactures of Novavax use human fetal derived cell lines or tissue in its development, manufacture or production?

The Novovax COVID-19 vaccine did not use human fetal cells lines or tissue in its development, manufacturing or production.[63]

Summary

In September 2021, COVID-19 was a substantial threat to staff and patients in health care institutions. Health care staff were disproportionately impacted by COVID-19 and patients in health care settings were at increased risk of serious disease and death because of underlying health conditions and/or age. Consequently, health care personnel were the first priority for vaccination by the ACIP and CDC when vaccine supplies were limited. There were three vaccines approved for use at the time, and they had been shown to be very safe and effective at preventing diseases, reducing transmission of disease, and serious consequences from COVID-19 including death. Consequently, unvaccinated persons in health care settings were at greater risk of COVID-19 themselves, and also posed risk to others they came into contact with. While many health care workers had already been infected at this time, natural immunity was poorly understood and not a substitute for vaccination. Mandatory COVID-19 vaccine policies were necessary in health care settings given the need for extremely high vaccine coverage necessary in health care settings and inadequate vaccine coverage that could be accomplished through education and access to free vaccine. The small number of persons with valid medical contraindications to vaccination must be given medical exemptions to mandatory policies. Health care institutions often also allowed religious exemptions for persons with sincerely held religious beliefs against vaccination. However, these health care institutions needed to limit exemptions to those persons with sincerely held religious beliefs that precluded vaccination in order to protect their staff and patients. Easily granting religious exemptions to all persons who requested them, including those without sincerely held religious beliefs precluding vaccination, would have undermined the vaccine requirement leading to substantial disease, disability and death among health care staff and patients.

[62] FDA News Release: Coronavirus (COVID-19) Update: FDA Authorizes Emergency Use of Novavax COVID-19 Vaccine, Adjuvanted. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-emergency-use-novavax-covid-19-vaccine-adjuvanted accessed 04/01/22

[63] Los Angeles County Department of Public Health. COVID-19 VACCINES AND FETAL CELL LINES. http://publichealth.lacounty.gov/media/coronavirus/docs/vaccine/VaccineDevelopment_FetalCellLines.pdf Accessed 04/01/23

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Global Disease Epidemiology and Control
Department of International Health
Department of Health, Behavior & Society
Institute for Vaccine Safety
The Johns Hopkins University
Bloomberg School of Public Health

Education and Training

2003 PhD, Health Policy and Management, Johns Hopkins University Bloomberg School of Public Health, Baltimore, MD
Dissertation: School Implementation of Immunization Requirements: Are School Policies or Personnel Associated with the Likelihood of a Child Claiming an Exemptions or School-Based Outbreaks of Measles or Pertussis?

1996 MPH, Health Policy and Management, Emory University Rollins School of Public Health, Atlanta, GA
Thesis: Health Consequences of Religious and Philosophical Exemptions from Immunization Laws: Individual and Societal Risk of Measles

1991 BA, Political Science with Minor in Psychology, Rutgers University, New Brunswick, NJ

Professional Experience

2018 - Director, Institute for Vaccine Safety, The Johns Hopkins University, Bloomberg School of Public Health

2017 - Professor, Global Disease Epidemiology and Control, Department of International Health, The Johns Hopkins University, Bloomberg School of Public Health

2017 - Professor, Health, Behavior and Society (joint appointment), The Johns Hopkins University, Bloomberg School of Public Health

2018 - 2021 Director of PhD Program, Global Disease Epidemiology and Control, Department of International Health, The Johns Hopkins University, Bloomberg School of Public Health

2012 - 2018	Deputy Director, Institute for Vaccine Safety, The Johns Hopkins University, Bloomberg School of Public Health
2012 - 2017	Associate Professor, Global Disease Epidemiology and Control, Department of International Health, The Johns Hopkins University, Bloomberg School of Public Health
2013 - 2017	Associate Professor, Health, Behavior and Society (joint appointment), The Johns Hopkins University, Bloomberg School of Public Health
2007 - 2012	Director of Vaccine Safety (GS 15 – Step 10), National Vaccine Program Office, Office of the Assistant Secretary for Health, Department of Health and Human Services
2007 - 2012	Adjunct Associate Professor, Global Disease Epidemiology and Control, Department of International Health, The Johns Hopkins University, Bloomberg School of Public Health
2005 - 2007	Associate Professor, Department of Epidemiology and Health Policy Research, University of Florida, College of Medicine
2003 - 2005	Assistant Scientist, Division of Disease Prevention and Control, Department of International Health, Associate Director for Policy and Behavioral Research, Institute for Vaccine Safety, The Johns Hopkins University, Bloomberg School of Public Health
2001 - 2003	Research Associate, Division of Disease Prevention and Control, Department of International Health, Associate Director for Policy and Behavioral Research, Institute for Vaccine Safety, The Johns Hopkins University, Bloomberg School of Public Health
1999 - 2001	Consultant, Institute for Vaccine Safety, The Johns Hopkins University, Bloomberg School of Public Health
2000	Consultant, Merck Vaccine Division, Merck and Co, Inc.
1997 - 1999	Policy Analyst, National Vaccine Program Office, Centers for Disease Control and Prevention
1995 -1997	Contractor, National Immunization Program, Centers for Disease Control and Prevention
1994 - 1995	HIV Prevention Community Coordinator, Health Visions, Inc.
1994	Consultant, Health Visions, Inc.

1990 - 1992 Residential Aide/Counselor, Alternatives, Inc.

Professional Activities

Society Membership
American Public Health Association, Member (1995-1999)
Infectious Disease Society of America, Member (2005-2007)

Advisory Panels
Parents of Kids with Infectious Diseases (PKIDS), Board Member (2007-)
Brighton Collaboration, Board Member, Vaccine Hesitancy Working Group Co-Chair (2012-)
Janssen Vaccine Policy Board Member (2021-)
Merck Vaccine Policy Board Member (2007)
39th National Immunization Conference External Planning Committee (2004)

Editorial Activities

Peer Reviewer (selected)
American Journal of Preventive Medicine
American Journal of Public Health
Archives of Pediatric and Adolescent Medicine
Biosecurity and Bioterrorism
BMC Family Practice
BMC Public Health
Expert Reviews of Vaccines
Health Affairs
Health Education Research
Indian Journal of Medical Science
Journal of Comparative Family Studies
Journal of Health Communication
Journal of the American Medical Association
Journal of the National Medical Association
Journal of Urban Health
New England Journal of Medicine
Pediatrics Pediatric Infectious Disease Journal
Pediatrics International
Public Health Reports
The Lancet
The Lancet, Infectious Diseases
Vaccine
Vaccines

Editorial Board
Vaccine, Associate Editor (2021- present)
Vaccines (2012-2013)

Guest Editor
Pediatrics Supplement: Vaccine Safety Throughout the Product Life Cycle (2011)
Vaccines Supplement: Confidence in Vaccines (2013)

Review of Proposals (selected)

National Institutes of Health, Dissemination & Implementation in Heath Study Section (DIHR). Special Emphasis Panels for National Institutes of Health, Centers for Disease Control and Prevention, Food and Drug Administration (Chair), National Science Foundation, and Canadian Institutes of Health Research.

Honors and Awards

- Haddon Fellow, Johns Hopkins University Bloomberg School of Public Health (1999-2001)
- Achievement Award – Dedication to Students, Johns Hopkins Bloomberg School of Public Health (2005)
- Development of the Federal Immunization Safety Task Force, Assistant Secretary for Health (2008)
- Federal Monitoring of H1N1 Vaccine Safety, Assistant Secretary for Health (2010)
- Patient Education Working Group Co-Chair, Assistant Secretary for Health (2012)
- Outstanding recent graduate (within past 10 years), Johns Hopkins Bloomberg School of Public Health (2013)
- Delta Omega Society (2014)

Publications (* indicated student/advisee/mentee)

***JOURNAL ARTICLES** (PEER REVIEWED)*

1. Dudley MZ, Gerber JE, Budigan Ni H, Blunt M, Holroyd TA, Carleton BC, Poland GA, **Salmon DA.** Vaccinomics: A scoping review. Vaccine. 2023 Mar 31;41(14):2357-2367.
2. Schwartz B, Brewer J, Budigan H, Bernier R, Dudley MZ, Kan L, Proveaux TM, Roberts R, Tafoya N, Hamlin MD, Moore L, Hughes M, Turner B, Al-Dahir S, Velasco E, Privor-Dumm L, Veloz W, White JA, Dubois S, Ooton J, Kipp BJ, Show TJ, Salu K, Chavez B, Montes MDP, Najera R, King T, **Salmon DA**. Factors Affecting SARS-CoV-2 Vaccination Intent and Decision Making Among African American, Native American, and Hispanic Participants in a Qualitative Study. Public Health Rep. 2023 Mar 27:333549231160871.
3. Carpiano RM, Callaghan T, DiResta R, Brewer NT, Clinton C, Galvani AP, Lakshmanan R, Parmet WE, Omer SB, Buttenheim AM, Benjamin RM, Caplan A, Elharake JA, Flowers LC, Maldonado YA, Mello MM, Opel DJ, **Salmon DA**, Schwartz JL, Sharfstein JM, Hotez PJ. Confronting the evolution and expansion of anti-vaccine activism in the USA in the COVID-19 era. Lancet. 2023 Mar 18;401(10380):967-970.
4. Kitano T, Thompson DA, Engineer L, Dudley M, **Salmon DA**. Risk and benefit of mRNA COVID-19 vaccines for Omicron variant by age, sex and presence of comorbidity: a quality-adjusted life years analysis. Am J Epidemiol. 2023 Mar 14:kwad058.
5. **Salmon DA**, Plotkin S, Navar AM. Vaccine Decision-making in a Time of Conflicting Recommendations: A Call to Go Beyond Politics. Pediatr Infect Dis J. 2023 Feb 22:e003892.

6. Dudley MZ, Schuh HB, Shaw J, Rimal RN, Harvey SA, Balgobin KR, Zapf AJ, **Salmon DA**. COVID-19 vaccination among different types of US Healthcare Personnel. Vaccine. 2023 Feb 17;41(8):1471-1479.
7. Dudley MZ, Barnett EE, Paulenich A, Omer SB, Schuh H, Proveaux TM, Buttenheim AM, Klein NP, Delamater P, McFadden SM, Patel KM, **Salmon DA**. Characterization of parental intention to vaccinate elementary school aged children in the state of California. Vaccine. 2023 Jan 16;41(3):630-635.
8. Budigan Ni H, de Broucker G, Patenaude BN, Dudley MZ, Hampton LM, **Salmon DA**. Economic impact of vaccine safety incident in Ukraine: The economic case for safety system investment. Vaccine. 2023 Jan 4;41(1):219-225.
9. Opel DJ, Brewer NT, Buttenheim AM, Callaghan T, Carpiano RM, Clinton C, Elharake JA, Flowers LC, Galvani AP, Hotez PJ, Schwartz JL, Benjamin RM, Caplan A, DiResta R, Lakshmanan R, Maldonado YA, Mello MM, Parmet WE, **Salmon DA**, Sharfstein JM, Omer SB. The legacy of the COVID-19 pandemic for childhood vaccination in the USA. Lancet. 2023 Jan 7;401(10370):75-78.
10. **Salmon DA**, Schuh HB, Sargent RH, Konja A, Harvey SA, Laurie S, Mai BS, Weakland LF, Lavery JV, Orenstein WA, Breiman RF. Impact of vaccine pause due to Thrombosis with thrombocytopenia syndrome (TTS) following vaccination with the Ad26.COV2.S vaccine manufactured by Janssen/Johnson & Johnson on vaccine hesitancy and acceptance among the unvaccinated population. PLoS One. 2022 Oct 11;17(10):e0274443.
11. Mello MM, Opel DJ, Benjamin RM, Callaghan T, DiResta R, Elharake JA, Flowers LC, Galvani AP, **Salmon DA**, Schwartz JL, Brewer NT, Buttenheim AM, Carpiano RM, Clinton C, Hotez PJ, Lakshmanan R, Maldonado YA, Omer SB, Sharfstein JM, Caplan A. Effectiveness of vaccination mandates in improving uptake of COVID-19 vaccines in the USA. Lancet. 2022 Aug 13;400(10351):535-538.
12. Omer SB, O'Leary ST, Bednarczyk RA, Ellingson MK, Spina CI, Dudley MZ, Chamberlain AT, Limaye RJ, Brewer SE, Frew PM, Malik FA, Orenstein W, Halsey N, Ault K, **Salmon DA**. Multi-tiered intervention to increase maternal immunization coverage: A randomized, controlled trial. Vaccine. 2022 Aug 12;40(34):4955-4963.
13. Sargent RH, Laurie S, Weakland LF, Lavery JV, **Salmon DA**, Orenstein WA, Breiman RF. Use of Random Domain Intercept Technology to Track COVID-19 Vaccination Rates in Real Time Across the United States: Survey Study. J Med Internet Res. 2022 Jul 1;24(7):e37920.
14. Dudley MZ, Schwartz B, Brewer J, Kan L, Bernier R, Gerber JE, Ni HB, Proveaux TM, Rimal RN, **Salmon DA**. COVID-19 Vaccination Status, Attitudes, and Values among US Adults in September 2021. J Clin Med. 2022 Jun 28;11(13):3734.
15. Sargent RH, Laurie S, Moncada L, Weakland LF, Lavery JV, **Salmon DA,** Orenstein WA, Breiman RF. Masks, money, and mandates: A national survey on efforts to increase COVID-19 vaccination intentions in the United States. PLoS One. 2022 Apr 21;17(4):e0267154.
16. Brewer NT, Buttenheim AM, Clinton CV, Mello MM, Benjamin RM, Callaghan T, Caplan A, Carpiano RM, DiResta R, Elharake JA, Flowers LC, Galvani AP, Hotez PJ, Lakshmanan R, Maldonado YA, Omer SB, **Salmon DA,** Schwartz JL, Sharfstein JM, Opel DJ. Incentives for COVID-19 vaccination. Lancet Reg Health Am. 2022 Apr;8:100205.

17. Trent MJ, **Salmon DA**, MacIntyre CR. Predictors of pneumococcal vaccination among Australian adults at high risk of pneumococcal disease. Vaccine. 2022 Feb 16;40(8):1152-1161.
18. Patel KM, McFadden SM, Mohanty S, Joyce CM, Delamater PL, Klein NP, **Salmon DA**, Omer SB, Buttenheim AM. Evaluation of Trends in Homeschooling Rates After Elimination of Nonmedical Exemptions to Childhood Immunizations in California, 2012-2020. JAMA Netw Open. 2022 Feb 1;5(2):e2146467.
19. **Salmon DA**, Black S, Didierlaurent AM, Moulton LH. Commentary on "Common vaccines and the risk of dementia: a population-based cohort study": Science can be messy but eventually leads to truths. J Infect Dis. 2022 Dec 21:jiac487.
20. Dudley MZ, Omer SB, O'Leary ST, Limaye RJ, Ellingson MK, Spina CI, Brewer SE, Bednarczyk RA, Chamberlain AT, Malik F, Frew PM, Church-Balin C, Riley LE, Ault KA, Orenstein WA, Halsey NA, **Salmon DA**. MomsTalkShots, tailored educational app, improves vaccine attitudes: a randomized controlled trial. BMC Public Health. 2022 Nov 21;22(1):2134.
21. Trent M, Seale H, Chughtai AA, **Salmon D**, MacIntyre CR. Trust in government, intention to vaccinate and COVID-19 vaccine hesitancy: A comparative survey of five large cities in the United States, United Kingdom, and Australia. Vaccine. 2022 Apr 14;40(17):2498-2505.
22. Brewer NT, Buttenheim AM, Clinton CV, Mello MM, Benjamin RM, Callaghan T, Caplan A, Carpiano RM, DiResta R, Elharake JA, Flowers LC, Galvani AP, Hotez PJ, Lakshmanan R, Maldonado YA, Omer SB, **Salmon DA**, Schwartz JL, Sharfstein JM, Opel DJ. Incentives for COVID-19 vaccination. Lancet Reg Health Am. 2022 Apr;8.
23. Patel KM, McFadden SM, Mohanty S, Joyce CM, Delamater PL, Klein NP, **Salmon DA**, Omer SB, Buttenheim AM. Evaluation of Trends in Homeschooling Rates After Elimination of Nonmedical Exemptions to Childhood Immunizations in California, 2012-2020. JAMA Netw Open. 2022 Feb 1;5(2).
24. Trent MJ, **Salmon DA**, MacIntyre CR. Predictors of pneumococcal vaccination among Australian adults at high risk of pneumococcal disease. Vaccine. 2022 Feb 16;40(8):1152-1161.
25. **Salmon DA**, Elharake JA, Brewer NT, Carpiano RM, DiResta R, Maldonado YA, Sgaier SK, Omer SB Vaccine Verification in the COVID-19 World. Lancet Commission on Vaccine Refusal, Acceptance, and Demand in the USA. Lancet Reg Health Am. 2022 Feb;6.
26. Omer SB, Benjamin RM, Brewer NT, Buttenheim AM, Callaghan T, Caplan A, Carpiano RM, Clinton C, DiResta R, Elharake JA, Flowers LC, Galvani AP, Lakshmanan R, Maldonado YA, McFadden SM, Mello MM, Opel DJ, Reiss DR, **Salmon DA**, Schwartz JL, Sharfstein JM, Hotez PJ. Promoting COVID-19 vaccine acceptance: recommendations from the Lancet Commission on Vaccine Refusal, Acceptance, and Demand in the USA. 2021 Dec 11;398(10317):2186-2192.
27. Sharfstein JM, Callaghan T, Carpiano RM, Sgaier SK, Brewer NT, Galvani AP, Lakshmanan R, McFadden SM, Reiss DR, **Salmon DA**, Hotez PJ. Uncoupling vaccination from politics: a call to action. Lancet Commission on Vaccine Refusal, Acceptance, and Demand in the USA. Lancet. 2021 Oct 2;398(10307):1211-1212.
28. **Salmon D**, Opel DJ, Dudley MZ, Brewer J, Breiman R. Reflections On Governance, Communication, And Equity: Challenges And Opportunities In COVID-19 Vaccination.

Health Aff (Millwood). 2021 Mar;40(3):419-425. doi: 10.1377/hlthaff.2020.02254. Epub 2021 Feb 4.

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30. Dudley MZ, Bernier R, Brewer J, **Salmon DA.** Walking the Tightrope: Reevaluating science communication in the era of COVID-19 vaccines. Vaccine. 2021 Sep 15;39(39):5453-5455.
31. Wu Q, Dudley MZ, Chen X, Bai X, Dong K, Zhuang T, Salmon D, Yu H. Evaluation of the safety profile of COVID-19 vaccines: a rapid review. BMC Med. 2021 Jul 28;19(1):173.
32. **Salmon DA**, Lambert PH, Nohynek HM, Gee J, Parashar UD, Tate JE, Wilder-Smith A, Hartigan-Go KY, Smith PG, Zuber PLF. Novel vaccine safety issues and areas that would benefit from further research. BMJ Glob Health. 2021 May;6(Suppl 2):e003814.
33. Gerber JE*, Brewer J, Limaye RJ, Sutherland A, Blunt M, Holroyd TA*, Geller G, Carleton B, Kahn J, **Salmon DA.** Vaccinomics: a cross-sectional survey of public values. Hum Vaccin Immunother. 2021 Jun 21:1-17.
34. Holroyd TA*, Limaye RJ, Gerber JE*, Rimal RN, Musci RJ, Brewer J, Sutherland A, Blunt M, Geller G, **Salmon DA.** Development of a Scale to Measure Trust in Public Health Authorities: Prevalence of Trust and Association with Vaccination. J Health Commun. 2021 May 16:1-9.
35. Limaye RJ, Opel DJ, Dempsey A, Ellingson M, Spina C, Omer SB, Dudley MZ, **Salmon DA**, Leary SO. Communicating With Vaccine-Hesitant Parents: A Narrative Review. Acad Pediatr. 2021 May-Jun;21(4S):S24-S29.
36. **Salmon DA**, Dudley MZ, Brewer J, Kan L, Gerber JE, Budigan H*, Proveaux TM, Bernier R, Rimal R, Schwartz B. COVID-19 vaccination attitudes, values and intentions among United States adults prior to emergency use authorization. Vaccine. 2021 Mar 24:S0264-410X(21)00315-7..
37. Gerber JE*, Brewer J, Limaye RJ, Sutherland A, Geller G, Spina CI, **Salmon DA.** Ethical and policy implications of vaccinomics in the United States: community members' perspectives. Hum Vaccin Immunother. 2021 Feb 24:1-12.
38. Trent MJ*, **Salmon DA**, MacIntyre CR. Using the health belief model to identify barriers to seasonal influenza vaccination among Australian adults in 2019. Influenza Other Respir Viruses. 2021 Feb 15.
39. Dudley MZ, Limaye RJ, **Salmon DA**, Omer SB, O'Leary ST, Ellingson MK, Spina CI, Brewer SE, Bednarczyk RA, Malik F, Frew PM, Chamberlain AT. Racial/Ethnic Disparities in Maternal Vaccine Knowledge, Attitudes, and Intentions. Public Health Rep. 2021 Jan 28.
40. Holroyd TA*, Howa AC, Proveaux TM, Delamater PL, Klein NP, Buttenheim AM, Limaye RJ, Omer SB, **Salmon DA**. School-level perceptions and enforcement of the elimination of nonmedical exemptions to vaccination in California. Hum Vaccin Immunother. 2021 Jan 25:1-8.
41. Shaw J, Stewart T, Anderson KB, Hanley S, Thomas SJ, **Salmon DA**, Morley C. Assessment of U.S. health care personnel (HCP) attitudes towards COVID-19 vaccination in a large university health care system. Clin Infect Dis. 2021 Jan 25. :

42. Dudley MZ, Taitel MS, Smith-Ray R, Singh T, Limaye RJ, **Salmon DA**. Effect of educational and financial incentive-based interventions on immunization attitudes, beliefs, intentions and receipt among close contacts of pregnant women. Vaccine. 2021 Feb 5;39(6):961-967.
43. Holroyd TA*, Howa AC, Delamater PL, Klein NP, Buttenheim AM, Limaye RJ, Proveaux TM, Omer SB, **Salmon DA**. Parental vaccine attitudes, beliefs, and practices: initial evidence in California after a vaccine policy change. Hum Vaccin Immunother. 2020 Nov 24:1-6.
44. Spina CI, Brewer SE, Ellingson MK, Chamberlain AT, Limaye RJ, Orenstein WA, **Salmon DA**, Omer SB, O'Leary ST. Adapting Center for Disease Control and Prevention's immunization quality improvement program to improve maternal vaccination uptake in obstetrics. Vaccine. 2020 Nov 25;38(50):7963-7969.
45. Kochhar S, **Salmon DA**. Planning for COVID-19 vaccines safety surveillance. Vaccine. 2020 Sep 11;38(40):6194-6198.
46. Dudley MZ, Limaye RJ, **Salmon DA**, Omer SB, O'Leary ST, Ellingson MK, Spina CI, Brewer SE, Bednarczyk RA, Malik F, Frew PM, Chamberlain AT. Latent Class Analysis of Maternal Vaccine Attitudes and Beliefs. Health Educ Behav. 2020 Oct;47(5):765-781.
47. Bleser WK, **Salmon DA**, Miranda PY. A hidden vulnerable population: Young children up-to-date on vaccine series recommendations except influenza vaccines. PLoS One. 2020 Jun 18;15(6):e0234466.
48. Limaye RJ, Malik F, Frew PM, Randall LA, Ellingson MK, O'Leary ST, Bednarczyk RA, Oloko O, **Salmon DA**, Omer SB. Patient Decision Making Related to Maternal and Childhood Vaccines: Exploring the Role of Trust in Providers Through a Relational Theory of Power Approach. Health Educ Behav. 2020 Jun;47(3):449-456.
49. Dudley MZ, Halsey NA, Omer SB, Orenstein WA, O'Leary ST, Limaye RJ, **Salmon DA**. The state of vaccine safety science: systematic reviews of the evidence. Lancet Infect Dis. 2020 May;20(5):e80-e89.
50. Dudley MZ*, Limaye RJ, Omer SB, O'Leary ST, Ellingson MK, Spina CI, Brewer SE, Chamberlain AT, Bednarczyk RA, Malik F, Frew PM, Salmon DA. Factors associated with referring close contacts to an app with individually-tailored vaccine information. Vaccine. 2020 Mar 17;38(13):2827-2832.
51. Holroyd TA*, Oloko OK, **Salmon DA**, Omer SB, Limaye RJ. Communicating Recommendations in Public Health Emergencies: The Role of Public Health Authorities. Health Secur. 2020 Jan/Feb;18(1):21-28.
52. Dudley MZ*, Limaye RJ, Omer SB, O'Leary ST, Ellingson MK, Spina CI, Brewer SE, Chamberlain AT, Bednarczyk RA, Malik F, Frew PM, **Salmon DA**. Characterizing the vaccine knowledge, attitudes, beliefs, and intentions of pregnant women in Georgia and Colorado. Hum Vaccin Immunother. 2020 Feb 20:1-9.
53. Mohanty S, Joyce CM, Delamater PL, Klein NP, **Salmon D**, Omer SB, Buttenheim AM. Homeschooling parents in California: Attitudes, beliefs and behaviors associated with child's vaccination status. Vaccine. 2020 Feb 18;38(8):1899-1905.
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55. Delamater PL, Buttenheim AM, Klein NP, Mohanty S, **Salmon DA**, Omer SB. Assessment of Exemptions from Vaccination in California, 2015 to 2027. Ann Intern Med. 2019 Nov 5.

56. **Salmon DA**, Limaye RJ, Dudley MZ*, Oloko OK, Church-Balin C, Ellingson MK, Spina CI, Brewer SE, Orenstein WA, Halsey NA, Chamberlain AT, Bednarczyk RA, Malik FA, Frew PM, O'Leary ST, Omer SB. MomsTalkShots: An individually tailored educational application for maternal and infant vaccines. Vaccine. 2019 Oct 8;37(43):6478-6485.
57. Pingali SC, Delamater PL, Buttenheim AM, **Salmon DA**, Klein NP, Omer SB. Associations of Statewide Legislative and Administrative Interventions with Vaccination Status Among Kindergartners in California. JAMA. 2019 Jul 2;322(1):49-56.
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61. Herman R, McNutt LA, Mehta M, **Salmon DA**, Bednarczyk RA, Shaw J. Vaccination perspectives among adolescents and their desired role in the decision-making process. Hum Vaccin Immunother. 2019 Feb 8
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64. Bleser WK*, Miranda PY, **Salmon DA**. Child Influenza Vaccination and Adult Work Loss: Reduced Sick Leave Use Only in Adults With Paid Sick Leave. Am J Prev Med. 2019 Feb;56(2):251-261.
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67. Kasting ML, Christy SM, Sutton SK, Lake P, Malo TL, Roetzheim RG, Schechtman T, Zimet GD, Walkosz BJ, **Salmon D**, Kahn JA, Giuliano AR, Vadaparampil ST. Florida physicians' reported use of AFIX-based strategies for human papillomavirus vaccination. Prev Med. 2018 Nov;116:143-149.
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COMMENTARIES

1. Gostin LO, Shaw J, **Salmon DA.** Mandatory SARS-CoV-2 Vaccinations in K-12 Schools, Colleges/Universities, and Businesses. JAMA. 2021 Jun 7. *Invited*
2. Gostin LO, **Salmon DA**, Larson HJ. Mandating COVID-19 Vaccines. JAMA. 2021 Feb 9;325(6):532-533. doi: 10.1001/jama.2020.26553. PMID: 33372955. *Invited*
3. Opel DJ, **Salmon DA**, Marcuse EK. Building Trust to Achieve Confidence in COVID-19 Vaccines. JAMA Netw Open. 2020 Oct 1;3(10):e2025672. doi: *Invited*
4. **Salmon DA**, Dudley MZ, Carleton BC. Guillain-Barré Syndrome Following Influenza Vaccines Affords Opportunity to Improve Vaccine Confidence. J Infect Dis. 2021 Feb 13;223(3):355-358. doi: 10.1093/infdis/jiaa544. PMID: 33137189. *Invited*
5. **Salmon DA**, Dudley MZ. It is time to get serious about vaccine confidence. Lancet. 2020 Sep 26;396(10255):870-871. doi: 10.1016/S0140-6736(20)31603-2. Epub 2020 Sep 10. PMID: 32919522. *Invited*
6. Gostin LO, **Salmon DA**. The Dual Epidemics of COVID-19 and Influenza: Vaccine Acceptance, Coverage, and Mandates. JAMA. 2020 Jul 28;324(4):335-336. doi: 10.1001/jama.2020.10802. PMID: 32525519. *Invited*
7. **Salmon DA**, MacIntyre CR, Omer SB. Making mandatory vaccination truly compulsory: well intentioned but ill conceived. Lancet Infect Dis. 2015 Aug;15(8):872-3.
8. Halsey NA, **Salmon DA**. Measles at Disneyland, a problem for all ages. Ann Intern Med. 2015 May 5;162(9):655-6. *Invited*
9. Atwell JE*, **Salmon DA**. Pertussis resurgence and vaccine uptake: implications for reducing vaccine hesitancy. Pediatrics. 2014 Sep; 134(3): 602-4. *Invited*
10. **Salmon DA**, Halsey. Guillain-Barré Syndrome and vaccination. Clin Infect Dis. 2013 Jul; 57(2):205-7. *Invited*

11. **Salmon DA**, Halsey NA. Keeping the M in medical exemptions: protecting our most vulnerable children. J Infect Dis. 2012 Oct 1; 206(7): 987-8.
12. MacIntyre CR, Kelly H, Jolley D, Butzkueven H, **Salmon D**, Halsey N, Moulton LH Recombinant hepatitis B vaccine and the risk of multiple sclerosis: a prospective study. Neurology. 2005 Apr 12;64(7):1317.

BOOKS

The Clinician's Vaccine Safety Resource Guide: Optimizing the Prevention of Vaccine-Preventable Diseases Across the Lifespan. Mathew Z. Dudley. **Daniel A Salmon**, Neal A. Halsey, alter A. Orenstein, Rupali J. Limaye, Sean T. O'Leary, Saad B. Omer. Springer Publishing, 2018.

GOVERNMENT AND ADVISORY COMMITTEE REPORTS

1. White Paper on the United States Vaccine Safety System. National Vaccine Advisory Committee (NVAC), 2012. Role: Served as the Designated Federal Official for the Vaccine Safety Working Group with responsibilities including determining the charge and membership of the working group, holding closed and public meetings to gather scientific and programmatic information and incorporation of stakeholder views, and oversaw drafting of final report.
2. H1N1 Vaccine Safety Risk Assessment Working Group (VSRAWG). National Vaccine Advisory Committee (NVAC). Interim reports (12/2009, 1/2010, 2/2010, 3/2010, 4/2010, 6/2010) and final report (1/2012). Role: Served as the Designated Federal Official with responsibilities including determining the charge and membership of the VSRAWG, coordinating bi-monthly conference calls with the Federal Immunization Safety Task Force and the VSRAWG reviewing all H1N1 safety data, facilitated discussions of safety issues among the VSRAWG, drafting all reports.
3. Recommendations on 2009 H1N1 Influenza Vaccine Safety Monitoring. National Vaccine Advisory Committee (NVAC). 7/2009. Role: Served as the Designated Federal Official for the Vaccine Safety Working Group with responsibilities including determining the charge and membership of the Working Group, holding meetings with Working Group and HHS leadership, and drafting final report.
4. Federal Plans to Monitor Immunization Safety for Pandemic 2009 H1N1 Influenza Vaccination Program. Department of Health and Human Services, 2009. Role: Primary author with the Federal Immunization Safety Task Force.
5. Recommendations on the Centers for Disease Control and Prevention Immunization Safety Office Draft 5-Year Scientific Agenda. National Vaccine Advisory Committee (NVAC), 2009. Role: Served as the Designated Federal Official for the Vaccine Safety Working Group with responsibilities including determining the charge and membership of the working group, holding closed and public meetings to gather scientific and programmatic information and incorporation of stakeholder views, and oversaw drafting final report.
6. A Comprehensive Review of Federal Vaccine Safety Programs and Pubic Health Activities. Department of Health and Human Services, 2008. Role: Primary author with the Federal Immunization Safety Task Force.

7. Vaccine Safety Action Plan (Implementation Plan for the Task Force Report on Safer Childhood Vaccines). Department of Health and Human Services, 1999. Role: Primary author with the many HHS agencies (NIH, FDA, CDC, HRSA).

Practice Activities

Dr. Salmon's public health practice has been carried out while he held positions in the Federal government and academia and has resulted in 15 peer reviewed publications, 7 Federal and advisory committee reports, dozens of testimony to Federal advisory committees and state legislators, regular consultation with policy-makers, and more than 50 interviews with national media outlets. This practice work has been funded by state and Federal government agencies, has been integrated into Dr. Salmon's teaching, and has resulted in several awards for outstanding services by the Assistant Secretary for Health. Dr. Salmon's leadership has impacted policy and public health practice nationally. Dr. Salmon has assisted in the development of model state laws for school immunization requirements, based upon public health scholarship, and evaluated the impact of the application of this model. Dr. Salmon was a major contributor to realigning vaccine safety activities within the Centers for Disease Control and Prevention in order to provide greater public confidence in vaccine safety, surveillance and response activities.

While serving as the Director of Vaccine Safety at the National Vaccine Program Office, Dr. Salmon led an inter-agency and inter-departmental Secretarial task force, The Federal Immunization Safety Task Force, responsible for ensuring the coordination and strategic planning of Federal vaccine safety activities. Under his leadership, this Task Force wrote a Secretarial report to enhance our vaccine safety systems and the safety chapter of the National Vaccine Plan. Dr. Salmon led the development of the National Vaccine Advisory Committee (NVAC) Vaccine Safety Working Group, issuing reports to the Assistant Secretary for Health to improve the national vaccine safety system and focus vaccine safety research activities. This Working Group was cited by RAND on how to effectively utilize the National Vaccine Advisory Committee. The Department of Health and Human Services has been able to garner and focus vaccine safety programmatic and research activities through these internal government and advisory committee reports.

The 2009-10 H1N1 vaccine program brought unusual challenges and opportunities for vaccine safety and Dr. Salmon's work. The last national effort to quickly vaccinate the country to prevent a novel swine flu pandemic in 1976 resulted in a public health and political failure as the vaccine caused Guillain-Barré syndrome (GBS) and the pandemic never materialized as anticipated. The New York Times referred to this as the Swine Flu Fiasco as the Director of the Centers for Disease Control and Prevention and the Surgeon General were dismissed as President Ford faced public criticism. A new administration and the public remembered this experience as the 2009-10 H1N1 vaccine program was launched with considerable skepticism. Dr. Salmon seized these challenges and was able to capitalize on them to ensure the safety monitoring was robust and credible and build long lasting infrastructure.

Dr. Salmon oversaw the largest and most comprehensive vaccine safety monitoring program (2009-10 H1N1 vaccine program) ever in the US or internationally. Dr. Salmon worked with seven agencies in the Department of Health and Human Services, as well as the Departments of

Defense and Veterans Affairs, to enhance active safety monitoring programs. Dr. Salmon developed a novel vaccine safety surveillance system, the Post Licensure Rapid Immunization Safety Monitoring (PRISM) Network that is now a part of permanent infrastructure at the Food and Drug Administration and has served as a model for drug and product safety monitoring. Dr. Salmon led the Federal Immunization Safety Task Force to develop a safety-monitoring plan for H1N1 that was shared with stakeholders and the public and once the program was launched. To enhance public and stakeholder engagement and improve public confidence, Dr. Salmon developed the H1N1 Vaccine Safety Risk Assessment Working Group of the National Vaccine Advisory Committee that provided independent oversight of all 2009-10 H1N1 vaccine data across the government every two weeks and provided publically deliberated reports on a monthly basis throughout the vaccine program. Dr. Salmon's work in this area was cited by an Institute of Medicine report reviewing the National Vaccine Plan and Federal vaccine activities as an area in vaccines with exemplary leadership and coordination. Many aspects of this 2009-10 H1N1 vaccine program that were instituted under his leadership continue today.

TESTIMONY

Dr. Salmon has made dozens of presentations to the National Vaccine Advisory Committee (NVAC), Advisory Commission on Childhood Vaccines (ACCV), the Advisory Committee on Immunization Practices (ACIP), and the National Biodefense Science Board (NBSB). He has also provided testimony for the Maryland and Florida Legislators.

PRESENTATIONS TO POLICY-MAKERS

Dr. Salmon has provided dozens of briefings for 3 CDC Directors, 3 Secretary's, two Deputy Secretary's, and 5 Assistant Secretary's for Health, U.S Department of Health and Human Services.

CONSULTATIONS WITH POLICY-MAKERS AND OTHER STAKEHOLDERS

Served as the Federal Ex-Officio for the Advisory Commission on Childhood Vaccines (ACCV; 2007-2012) which provides advice to the Secretary, HHS, regarding the Vaccine Injury Compensation Program (HRSA). Developed working groups (as the Designated Federal Official) of the National Vaccine Advisory Committee (NVAC) that provides policy advice to the Director of the National Vaccine Program/Assistant Secretary for Health to optimize the prevention of disease through vaccination and the prevention of vaccine adverse events. Through Dr. Salmon's leadership, the NVAC produced the following reports: 1) Review and prioritization of CDC Immunization Safety Office research agenda; 2) Recommendations for improving the Nations vaccine safety system; 3) Recommendations for improvements to H1N1 safety monitoring programs; and 4) Independent ongoing review of all H1N1 safety data. Through these Federal Advisory Committee efforts, Dr. Salmon worked closely with a very broad range of stakeholders including state and local health departments, Federal agencies (NIH, FDA, CDC, HRSA, IHS) and departments (HHS, DoD, VA, USAID), vaccine manufacturers, professional associations, academia, and advocacy organizations. Dr. Salmon has held many local, regional and national meetings to engage these stakeholders in vaccine policy and practice, issuing meeting reports, and impacting the policy and practice recommendation of the aforementioned advisory committee reports.

RESEARCH FINDING DISSEMINATION THROUGH MEDIA APPEARANCES

Dr. Salmon has made many media appearances and contributed to stories for CNN, Reuters News, The Associated Press, The New York Times, The Wall Street Journal, The Washington Post, The LA Times, and many other city, state and national media outlets.

SOFTWARE DEVELOPMENT

Developing and evaluating immunization App to increase maternal and infant vaccination uptake.

PRACTICE POSITIONS (OUTSIDE ACADEMIA)

Director of Vaccine Safety, National Vaccine Program Office, Office of the Assistant Secretary for Health, US Department of Health and Human Services (2007-2012): Coordinated, evaluated and provided leadership for federal vaccine safety programs.

- Developed a Secretarial Task Force (Federal Immunization Safety Task Force) issuing a report to the Secretary to enhance safety systems and providing ongoing coordination and leadership of Federal vaccine safety activities.
- Coordinated Federal H1N1 vaccine safety monitoring across multiple HHS Agencies and Departments, including development of federal strategic planning, addressing emerging issues, and development of innovative initiatives.
- Developed a novel active surveillance system (Post Licensure Rapid Immunization Safety Monitoring (PRISM)) for H1N1 vaccination program, capturing vaccine histories from 8 state immunization registries linked with health records for about 35 million persons through 5 large health insurance companies. This program is now a permanent part of vaccine safety monitoring by the FDA.
- Conducted a meta-analysis combining GBS data across multiple safety monitoring systems and worked with Vaccine Injury Compensation Program (HRSA) to determine if GBS should be a compensatable injury.
- Guest Edited supplement for Pediatrics to improve understanding of vaccine safety systems and science and enable effective communications by pediatricians when discussing vaccine safety with parents.

CURRICULUM VITAE

Daniel Salmon
Part II

Teaching

MASTERS ADVISEES
Ann Marie Navar, 2005
Jana Goins, 2005
Bernadette Cambell, 2005
Brian Rosen, 2013
Kevin Wright, 2013
Benjamin Williams, 2013
Mathew Dudley, 2013
Bansari Patel, 2013
Oladeji Oloko, 2014
Hannah Steinberg, 2014
Moar Sherbini, 2014
Aderemi Sanusi, 2016 (anticipated)
Caroline Picher, 2016 (anticipated)

DOCTORAL ADVISEES
Dustin Gibson, PhD, 2014
Matt Dudley, PhD, 2019
Andrea Carcelen, PhD, 2020
Jennifer Gerber, PhD, 2020
Taylor Halroyd, PhD, 2020

PRELIMINARY ORAL PARTICIPATION
Saad Omer, 2004
Dustin Gibson, 2012
Paul Messino, 2014 (alternate)
Cristina Garcia, 2015 (alternate)
Karen Chang, 2015 (alternate)
Talia Quandelacy, 2016 (alternate)
Elizabeth Chmielewski, 2016

FINAL ORAL PARTICIPATION
Saad Omer, 2006: "Societal Risk of Pertussis in the United States: Role of State Policies and Spatial Clustering of Childhood Vaccine Refusers"
Ann Marie Navar, 2009: "Impact of Immunization in the Neonatal Intensive Care Unit"
Zunera Gilani (alternate), 2012: "Population Immunity to Measles and Rubella Virus in Rural Zambia"
Noor Rakshani, DRPH, 2013: "Individual and Contextual Level Factors Influencing Initiation, Completion and Up to Date Vaccination in Routine Immunization Program"

Jennifer Kreslake (chair), 2014: "Determinants of Risk Behaviors in the Containment of Highly Pathogenic Avian Influenza and Implications for Risk Communication"
Dustin Gibson, 2014: "The Readiness, Need for, and Effect of mHealth Interventions to Improve Immunization Timeliness and Coverage in Rural Western Kenya"
Brittany Kmush, 2016: "Determinants of Immunologic Persistence of Hepatitis E Virus Antibodies." (alternate)

MSPH/POST-MPH INTERNSHIPS HIRED AND SUPERVISED (CURRENT POSITION, NUMBER OF CO-AUTHORED PAPERS)
Ann Marie Navar, 2006 (Cardiology Resident, Duke University; 5 papers)
Terrel Carter, 2007 (American Academy of Pediatrics, Global Immunization Staff; 4 papers)
Stephanie Irving, 2007 (Kaiser Permanente Center for Health Research; 1 paper)
Kirsten Vannice, 2008-10 (World Health Organization; 6 papers)
Michelle Mergler, 2009-10 (Johns Hopkins Doctoral Student; 2 papers)
Will Bleser, 2010 (Penn State Doctoral Student; 1 paper)

Classroom Instruction

PRIMARY INSTRUCTOR

2003 - Vaccine Policy Issues (223.687.01). This 3-credit course examines current national and international policy issues in vaccine research, development, manufacturing, supply, and utilization. Topics include development of orphan vaccines, ensuring an adequate supply of safe and effective vaccines, vaccine injury compensation, and disease eradication. Emphasizes the identification of important vaccine policy issues and the development and evaluation of policies to address these issues. Presents the roles, responsibilities, and policy positions of key immunization stakeholders via guest lectures by a wide array of experts who have worked for important vaccine groups (i.e., FDA, GAVI, Vaccine Industry, US Vaccine Injury Compensation Program, Consumer Group). 35-45 students masters and doctoral students from across the School of Public Health and Preventive Medicine Residents. Consistently received high student course evaluations.

2018 - The Practice of Public Health Through Vaccine Case Studies: Problem Solving Seminar (223.630.81). Vaccines are among the most effective medical and public health interventions. This class for DrPH students presents historic vaccine case studies highlighting challenges in emerging science, program design and evaluation, management, policy and communication. The seminar examines decision-making surrounded by scientific uncertainty, controversy and competing public health priorities and explores the challenges of developing policy and practice decisions within the constraints of emerging and uncertain science. Students are challenged to make policy decisions and develop programmatic and communication strategies in real world settings.

2012 - 2013 Vaccine Policy Issues (223.687.98). Johns Hopkins Fall Institute, Barcelona, Spain.

CO-INSTRUCTOR

2004-05 Public Health Practice (305.607.01). This 4 credit course focused on the areas of knowledge and skills necessary to the administration of health agencies. The course covered topics such as administrative structure, intergovernmental relations, legislation, politics, and the public budgetary process with reference to health departments on the federal, state, and local levels. The course also reviewed public sector issues for which health agencies are responsible, including AIDS, health promotion strategies, primary care, and immunization programs. Developed and taught class on-site and online.

Research Grant Participation

CURRENT

SARS-CoV2 Vaccines Information Equity and Demand Creation Project (COVIED)
Sponsor: Centers for Disease Control and Prevention
Role: Multiple Principal Investigator (mPIs Robert Breiman and Walter Orenstein) (25% effort)
Dates: 02/01/2021-09/31/201
Project: This project implements systematic approach to provide interpretable, context- and culture-specific accurate and trusted information about the vaccines that will be offered, and to package and deliver this information to susceptible populations at risk for COVID and demonstrating vaccine hesitancy as a means to substantively reduce the disproportionate impact of COVID illness and death associated with this pandemic.

Understanding Diverse Communities and Supporting Equitable and Informed COVID-19 Vaccination Decision-Making
Sponsor: Robert Wood Johnson Foundation
Role: Principal Investigator (20% effort)
Dates: 11/1/2020-9/1/2021
Project: Collaborating with NACCH, ASTHO, AIM and NIHB to better understand how people are approaching decision-making regarding COVID-19 vaccination and what additional information they need to make an informed decision for themselves, their family, and their community.

Public and Health Care Provider knowledge, attitudes, beliefs, intentions, and behaviors regarding COVID-19 disease and SARS-CoV-2 vaccines: the mediating role of trust in health care providers and public health authorities
Sponsor: Merck
Role: Principal Investigator (15% effort)
Dates: 01/01/2021-07/30/2022
Project: The primary objective of this study is to evaluate the immediate impact of outbreaks of COVID-19 disease and response measures on uptake of recommended vaccines, including but not limited to SARS-CoV-2 vaccines (when such vaccines are recommended), with a focus on trust in health care providers and public health authorities, and their vaccine knowledge, attitudes and beliefs.

Health Care Provider Training to Increase Vaccine Uptake and Reduce Vaccine Hesitancy

Sponsor: Merck
Role: Principal Investigator (15% effort)
Dates: 01/01/2021-07/30/2022
Project: The primary objective of this project is to develop, disseminate and evaluate a Continuing Medical Education (CME) training module and an electronically available Point-of-Care Information Technology (POC-IT) guide for health care providers (HCPs) to improve vaccine informed decision-making, vaccine acceptance, and control of vaccine preventable disease (VPD).

TweenVax: A comprehensive practice-, provider-, and parent/patient-level intervention to improve adolescent HPV vaccination
Sponsoring Agency: National Cancer Institute, National Institutes of Health
Role: Co-Investigator (5% effort)
Dates: 09/01/2019 – 06/30/2024
Project: The aim of the project is to develop and refine the practice-, provider-, and patient/parent-level intervention that will be tested in primary care pediatric and family practice offices for adolescents aged 9-14.

Valuation of Vaccine Safety
Sponsor: GAVI
Role: Principal Investigator (20% effort)
Dates: 07/15/2020 – 07/31/2021
Project: This project quantifies the health and economic costs associated with the vaccine safety disaster that occurred in the Ukraine in 2008 where there was a decline in vaccine public confidence triggered by mishandled death following a measles vaccine campaign, leading to a large measles outbreak including exportation to other countries.

Impact of Eliminating Non-Medical Exemptions in California
Sponsoring Agency: National Institute of Allergy and Infectious Diseases, National Institutes of Health
Role: Co-Investigator (20% effort)
Dates: 2016-2021
Project: California is the first state in decades to abolish non-medical exemptions to school immunization requirements. This study examines the implementation and impact of this change by assessing the burdens on health care providers, health departments, schools and parents and the rates of medical exemptions and home schooling.

Ethical, Legal and Social Issues (ELSI) for Precision Medicine and Infectious Disease: Centers for Excellence in ELSI Research (CEER)
Sponsoring Agency: National Human Genome Research Institute, National Institutes of Health
Role: Co-Investigator, Lead Vaccinomics (15% effort)
Dates: 2016-2020
Project: Anticipate and examine the ethical, legal, social, historical and policy issues confronting the incorporation of genomics in the prevention, outbreak control, and treatment of a range of infectious diseases, and plan for the responsible translation of genomic advances into practice.

A Comprehensive Pre-natal Intervention to Increase Vaccine Coverage
Sponsoring Agency: National Institutes of Health: Dissemination and Implementation Research in Health (R01)
Role: Multiple Principal Investigator (with Saad Omer, Emory University) (35% effort)
Dates: 2015-2020
Project: Develop and evaluate a comprehensive intervention at the patient, provider and practice levels to increase maternal and childhood vaccine uptake.

The Vaccine Safety Communication E-Library
Sponsor: WHO
Role: Principal Investigator (5% effort)
Dates: 02/01/2019 – 04/30/2019
Project: The objective is to work with the WHO vaccine safety office to develop the e-library by assisting with growing the content and enhancing the organization and searchability of the VSN e-library and the development of a plan of action to increase participation of members and new members.

Development and Writing of the Global Vaccine Safety Blueprint 2.0
Role: Principal Investigator (15% effort)
Dates: 07/16/2019 – 04/30/2020
Project: The objective of this project is to work with the Global Vaccine Safety Initiative team to develop and write the Global Vaccine Safety Blueprint 2.0.

Programmatic Impact of Multi-dose Vaccines
Sponsoring Agency: Bill and Melinda Gates Institute through the Johns Snow Institute
Role: Co-Investigator (10% effort)
Dates: 2016-2018
Project: To equip global and country level decision makers with the evidence, guidance, and tools needed to assess when, where, and how the selection of vaccine presentation affects timely, equitable, and safe vaccination coverage.

Case Studies of the Impact of Meningitis Epidemics on Local Health Departments and College Health Facilities
Sponsoring Agency: Pfizer
Role: Principal Investigator (25% effort)
Dates: 2015-2016
Project: Evaluate the non-medical costs associated with Meningitis outbreaks in university settings.

COMPLETED
Capitalizing on Recent Changes to School Immunization Requirements to Improve the Publics Health
Sponsoring Agency: Robert Wood Johnson Foundation Public Health Law Program
Role: Hopkins Principal Investigator (10% effort)
Dates: 2014-2016

Project: Evaluate the implementation and impact of recent changes made to state school immunization requirements and develop model school immunization law.

Evaluation of Parents Claiming Exemptions to School Entry Immunization Requirements
Sponsoring Agency: Centers for Disease Control and Prevention
Role: Principal Investigator (20% effort)
Dates: 2004-2006
Project: Examined the secular trends and geographical clustering of immunization exemptions and associations with pertussis, reasons why parents refuse vaccines, and conducted a content analysis of vaccine safety newspaper stories.

Mentored Patient-Oriented Research Career Development Award (K23). Decision Making of Parents to Vaccinate Their Children
Sponsoring Agency: National Institutes of Health
Role: Principal Investigator (75% effort)
Dates: 2004-2007
Project: Explored the role of health care providers in influencing parental vaccination decisions.

Policy and Ethical Consultation on Pandemic Planning and Public Health Emergencies
Sponsoring Agency: Florida Department of Health
Role: Principal Investigator (10% effort)
Dates: 2005-2006
Project: Explored ethical issues regarding responding to an influenza pandemic and developed a training module for public health workers to understand ethical issues surrounding vaccination during a pandemic.

Implementation of Mandatory Immunization Requirements
Sponsoring Agency: Centers for Disease Control and Prevention
Role: Co-Principal Investigator (with Neal Halsey) (75% effort)
Dates: 2001-2003
Project: Assessed the role of school personnel and school policies in implementing immunization requirements. Explored the reasons why some parents claim exemptions to school immunization requirements.

The Role of School Personnel and Policies in Implementing Immunization Requirements
Sponsoring Agency: Washington State Department of Health
Role: Principal Investigator (10% effort)
Dates: 2001-2004
Project: Explored the role of school personnel and school policies in implementing immunization requirements in Washington State.

Academic Service

2003 - 2005 Admissions Committee for MSPH Program, Disease Prevention and Control, Department of International Health, Johns Hopkins Bloomberg School of Public Health

2005 - 2007	Epidemiology Program Director, Interdisciplinary Program (IDP), University of Florida, College of Medicine
2012 -	Admissions Committee for PhD Program, Global Disease Epidemiology and Control, Department of International Health, Johns Hopkins Bloomberg School of Public Health
2014 -	Honors and Awards Committee, Department of International Health, Johns Hopkins Bloomberg School of Public Health
2015 -	Public Health Practice Committee, Johns Hopkins Bloomberg School of Health

Advisory Committee Presentations (selected)

National Vaccine Advisory Committee, Vaccine Confidence Working Group (2020-).

National Vaccine Advisory Committee, Adolescent Vaccine Working Group. History and Impact of School Immunization Requirements: Implications for Adolescent Vaccination. (2006)

National Vaccine Advisory Committee, Subcommittee on Vaccine Safety. Enhancing Public Confidence in Vaccines through Independent Oversight of Post-Licensure Vaccine Safety (2004).

National Vaccine Advisory Committee Working Group on Implementing Vaccine Recommendations, presentation to the Committee and expert witness for panel discussion (2002).

National Vaccine Advisory Committee Working Group on Philosophical Exemptions, presentation to the Committee (1998).

Personal Statement

Dr. Salmon's primary research and practice interest is optimizing the prevention of childhood infectious diseases through the use of vaccines. He is broadly trained in vaccinology, with an emphasis in epidemiology, behavioral epidemiology, and health policy. Dr. Salmon's focus has been on determining the individual and community risks of vaccine refusal, understanding factors that impact vaccine acceptance, evaluating and improving state laws providing exemptions to school immunization requirements, developing systems and science in vaccine safety, and effective vaccine risk communication. Dr. Salmon has considerable experience developing surveillance systems, using surveillance data for epidemiological studies, and measuring immunization coverage through a variety of approaches. Dr. Salmon has worked with state and federal public health agencies to strengthen immunization programs and pandemic planning.

Controversies have always existed around vaccines. However, increasingly parents are worried about the safety of vaccines and the rates of parents refusing vaccines have been increasing. Dr. Salmon's led the first study quantifying the individual and community risks of measles associated with vaccine refusal. He and others have replicated these studies examining the risk of vaccine refusers for pertussis, *Haemophilus influenzae* type b, varicella, and pneumococcal. Dr. Salmon's studies in this area have demonstrated that local clustering of refusal is associated with measles and pertussis, explaining why we see sporadic measles outbreaks despite very high vaccine coverage nationally. Dr. Salmon's work quantifying the individual and community risks of disease resulting from vaccine refusal has directly impacted national and state policy in this area.

Having quantified the magnitude of the problem of vaccine refusal, Dr. Salmon conducted a broad range of studies examining factors that contribute to vaccine acceptance and refusal. He conducted studies comparing parents who refused vaccines for their children compared to parents of fully vaccinated children. He then linked these parents to their health care providers to understand the impact of health care providers on parental vaccine decision-making. Dr. Salmon conducted studies exploring the impact of school-level personnel and policies on vaccine refusal and the impact of the media's focus on vaccine safety.

Dr. Salmon's investigations of parents who refuse vaccines for their children have included parents who claim exemptions to school immunization requirements because they are actively deciding to refuse vaccines altogether rather than delay vaccines. Dr. Salmon has investigated compulsory vaccination in the US compared to other developed countries. He has explored how school laws are implemented and enforced at the state and local level and how this impacts the rates of exemptions. He developed an evidence-based model state exemption law that has been implemented in various forms in many states to strengthen their state exemption laws. He has evaluated the impact of these applications of this model and is in the process of revising this model law with a broad range of stakeholders. Dr. Salmon's work in this area has largely shaped the debate we see in many states making exemption laws more stringent and offers a policy approach to limiting exemptions while preserving parental autonomy.

Concerns about the safety of vaccines are the primary (but not the only) reason that parents are increasingly refusing vaccines. Dr. Salmon has focused on developing the science base for

vaccine safety. He served as the Director for Vaccine Safety, National Vaccine Program Office, HHS, where he was responsible for coordinating and leading our national vaccine safety efforts including, but not limited to, the 2009 H1N1 vaccine program. In this capacity, Dr. Salmon improved our vaccine safety systems. During the H1N1 vaccine program he oversaw the largest, most comprehensive vaccine safety monitoring program ever in the US and the world. Dr. Salmon developed a new active surveillance system (Post-licensure Rapid Immunization Safety Monitoring (PRISM) Network) that is now a permanent part of our vaccine safety monitoring program. He created independent vaccine safety assessment to improve trust and confidence. The success of these efforts was highlighted by the IOM when reviewing the National Vaccine Plan. Dr. Salmon has also conducted safety studies, such as the most comprehensive evaluation of GBS post-influenza vaccine since 1976. Dr. Salmon is currently a board member of the Brighton Collaboration, an international network of vaccine safety investigators, and co-chairs their vaccine confidence working group.

While improving safety systems and science is essential to addressing parental safety concerns, it is necessary to effectively communicate the risks and benefits of vaccines to the scientific community, healthcare providers, the media and the public. To work toward this objective, Dr. Salmon has conducted vaccine risk perception and communication studies, developed communication strategies for the Department of Health and Human Services and its Agencies, and developed resources for healthcare providers. Dr. Salmon is currently focused on developing and evaluating interventions at the patient, provider and practice levels to improve maternal and infant vaccine acceptance. Dr. Salmon was the guest editor to a supplement in Pediatrics that assisted pediatricians in working with vaccine hesitant parents by reviewing the complex vaccine safety system in the US, reviewing factors that impact vaccine hesitancy, and assisting pediatricians with how to communicate with parents. Dr. Salmon is widely considered a national and international expert in vaccine safety and factors impacting vaccine acceptance.

Keywords

Vaccine, Immunization, Infectious Diseases, Epidemiology, Health Policy, Public Health Practice